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No. OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1994

PANTRON I CORPORATION, HAL Z. LEDERMAN,

Petitioners.

v.

FEDERAL TRADE COMMISSION,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

EDWARD A. WOODS*
ALLEN B. GRODSKY
BROWNE & WOODS
450 N. Roxbury Dr., 7th Fl.
Beverly Hills, CA 90210-4231
(310) 274-7100

Attorneys for Petitioners

*Counsel of Record

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

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QUESTIONS PRESENTED

1. Did the Ninth Circuit err in creating a new category of false advertisements under the Federal Trade Commission Act, 15 U.S.C. §§ 45 *et seq.* (the "FTCA"), that prohibits advertisements that accurately reflect a product's efficacy, where the product advertised indisputably poses no health or safety risk and where the users of the product are satisfied with its performance?

2. Did the Ninth Circuit err in placing the burden of proof in a false advertising claim under the FTCA on the advertiser to exclude the possibility that the advertised product's efficacy is due to the placebo effect?

3. Did the Ninth Circuit err in interpreting the FTCA to restrict the evidence upon which a defendant in a false advertisement claim can rely in proving the truth of advertisements of its product's efficacy to evidence acceptable to the *American* medical community?

4. Did the Court of Appeal err in holding – in contrast to the decisions of other circuits – that, under the FTCA, a trial court is mandated to award, and has no discretion to refuse to award, restitution and/or disgorgement of profits?

5. Did the Court of Appeal err in mandating that a seller disgorge its profits and pay restitution under the FTCA where the Ninth Circuit held that there is sufficient evidence in the record to show that the advertised product is effective as advertised, where there is no evidence of dissatisfied consumers, and where the product advertised indisputably poses no health or safety risk?

LIST OF PARTIES AND RULE 29.1 LIST

The parties to the proceedings below were the petitioners Pantron I Corporation and Hal Z. Lederman and respondent Federal Trade Commission.

Pursuant to Supreme Court Rule 29.1, Pantron I Corporation has no parent corporation or subsidiaries.

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PETITION FOR WRIT OF CERTIORARI

The petitioners Pantron I Corporation and Hal Z. Lederman respectfully pray that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Ninth Circuit, entered in the above-entitled proceeding on August 25, 1994.

OPINIONS BELOW

The opinion of the Court of Appeals for the Ninth Circuit is reported at 33 F.3d 1088, and a true and correct

copy of such opinion is attached hereto as part of the appendix.

The Judgment, Order for Judgment, Findings of Fact and Conclusions of Law, and Memorandum of Opinion and Intended Judgment (Gadbois, D.J.) have not been reported. True and correct copies of those documents are attached as part of the appendix.

JURISDICTION

Invoking jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b), the respondent brought this suit in the Central District of California. On July 27, 1992, the district court entered judgment, after a trial on the merits.

On respondent's appeal, the Ninth Circuit on August 25, 1994, affirmed in part and reversed in part the district court's judgment and directed the district court to modify its injunction and to order petitioners to pay monetary equitable relief.

Petitioners herein filed a petition for rehearing and suggestion for rehearing *en banc* on September 8, 1994, and that petition was denied on November 16, 1994.

On February 9, 1995, Justice O'Connor entered an Order extending petitioners' time to file a petition for writ of certiorari to and including March 16, 1995.

The jurisdiction of this Court to review the judgment of the Ninth Circuit is invoked under 28 U.S.C. § 1254(1).

STATUTES INVOLVED

15 U.S.C. § 45(a)(1). Unfair methods of competition unlawful; prevention by Commission.

Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in and affecting commerce, are declared unlawful.

15 U.S.C. § 52. Dissemination of false advertisements.

(a) Unlawfulness

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement –

> (1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, or cosmetics; or
>
> (2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce of food, drugs, devices, or cosmetics.

(b) Unfair or deceptive act or practice

The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

15 U.S.C. § 53. False advertisements; injunctions and restraining orders.

(b) Temporary restraining orders; preliminary injunctions

Whenever the Commission has reason to believe –

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public –

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however,* That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further,* That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. Any such suit shall be

brought in the district in which such person, partnership, or corporation resides or transacts business.

15 U.S.C. § 55(a)(1). Additional Definitions.

The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. . . .

STATEMENT OF THE CASE

This is a false advertising case brought by the Federal Trade Commission ("FTC") against Petitioner Pantron I Corporation ("Pantron") and its owner Hal Z. Lederman. Petitioners manufacture and sell the "Helsinki Formula," which is advertised as effective to decrease hair loss and promote new hair growth. All parties agree that the Helsinki Formula poses no health or safety risk to its users. (Findings of Fact, ¶ 24.)

In the court below, the FTC challenged Pantron's advertising about the efficacy of the Helsinki Formula.

But this is not the "run of the mill" case in which the FTC has filed a lawsuit in response to complaints by customers who claim to have been misled by false advertising. To the contrary, it is *undisputed* in this case that there is an extremely high level of consumer satisfaction among customers of the Helsinki Formula. This is manifested by, among other things, (1) a high level of customers who have ordered the Helsinki Formula on more than one occasion, (2) an extremely low level of complaints by Helsinki Formula customers, and (3) a very small number of customers taking advantage of the money back guarantee offered by Pantron.

Prompted not by unhappy consumers, but rather by lobbying by the Upjohn Company, a competitor of Pantron – and, according to the district court, the "prime mover in the FTC's action" (Findings of Fact, ¶ 23) – the FTC filed this case under 15 U.S.C. § 53(b), alleging that Pantron and Lederman falsely advertised (1) that the Helsinki Formula was effective, and (2) that such efficacy was established by "scientific" proof. The FTC sought injunctive relief as well as restitution and disgorgement of profits. Jurisdiction in United States District Court was based on 15 U.S.C. §§ 45(a) and 53(b); 28 U.S.C. §§ 1331, 1337(a), and 1345. (Conclusions of Law, ¶ 1.)

A trial on the merits was held in November 1989, before the Honorable Richard A. Gadbois, Jr., United States District Judge for the Central District of California. The district court held that the FTC had failed to carry its burden of proving the falsity of the representation in Pantron's advertisements that the Helsinki Formula is effective. The district court specifically held that *there was "no evidence in the record to support a contention that the*

Helsinki Formula is wholly ineffective." (Findings of Fact, ¶ 10, emphasis added.) It based that finding on the following:

(1) None of the FTC's experts had ever tested or studied the Helsinki Formula to determine its efficacy. (Findings of Fact, ¶ 15.)

(2) The FTC did not present a single Helsinki Formula user who testified that the product did not work. (Findings of Fact, ¶ 13.)

(3) The study relied on by the FTC at trial – a study of a *different* product – had numerous serious defects. (Findings of Fact, ¶ 16.)

The district court went on to find that "*the Helsinki Formula most probably works some of the time for a lot of people.*" (Findings of Fact, ¶ 13, emphasis added.) The court based this finding on:

(1) "*[M]edical investigative work done by responsible physicians in Europe.*" (Findings of Fact, ¶ 10.) The district court found that these European studies were conducted "by careful and experienced scientists working in good faith" and that the expert scientist who testified at trial for Pantron was "a credible witness as to her observations and the work of others in Europe." (Findings of Fact, ¶ 12.)

(2) *Surveys conducted of Pantron's users which showed the Helsinki Formula to be effective and its customers to be satisfied.* (Findings of Fact, ¶ 13.) Those surveys revealed that of those consumers who used the Helsinki Formula for more than four months, 66.7% received positive results.

(3) *Testimony of users of the Helsinki Formula about the positive results they received.* (Findings of Fact, ¶ 13.) As the district court noted: "It is hard to believe that such witnesses cannot tell whether the product works and are simply deluding themselves." (Findings of Fact, ¶ 13.)

The district court did, however, enjoin petitioners from advertising that the efficacy of its product is "scientifically proven." The district court further ordered that any advertisement of the Helsinki Formula's efficacy must be accompanied by a clear and conspicuous disclosure that the product's efficacy:

(1) is more likely to involve arrest of hair loss than growth of new hair, and

(2) is not explained or supported by scientific studies recognized under standards in use in the United States.

(Judgment, ¶ I.)

In addition, the district court rejected the FTC's request for restitution or disgorgement of profits. (Conclusions of Law, ¶ 11.) The district court stated that there was no reason for such relief, that the FTC failed to establish that Pantron's conduct caused deception or injury to consumers, and that the FTC failed to establish that Lederman knew or should have known that his conduct was fraudulent or dishonest. (Conclusions of Law, ¶ 11.)

The FTC appealed and the Ninth Circuit, in an opinion written by Judge Reinhardt, reversed in part and affirmed in part. The Ninth Circuit conceded that "there

was sufficient evidence in the record to support the district court's finding that use of the Helsinki Formula might arrest hair loss in some of the people some of the time." 33 F.3d 1088, 1097 (9th Cir. 1994).[1] Nevertheless, the Court of Appeals reversed the district court and instructed that Pantron be enjoined from advertising the efficacy of the Helsinki Formula with or without a disclaimer. 33 F.3d at 1101.

Judge Reinhardt's explanation for requiring that Pantron be enjoined from advertising what the record showed to be correct was as follows: Judge Reinhardt, in effect shifting the usual burden of proof from the FTC to Pantron, concluded that Pantron had failed to exclude the possibility that the efficacy of the Helsinki Formula solely resulted from the "placebo effect." In other words, the Ninth Circuit concluded that, while the evidence may have shown that users of the Helsinki Formula achieve new hair growth or decreased hair loss, Pantron failed to exclude the possibility that such results stem not from any "inherent merit" in the Helsinki Formula, but rather occur for "psychological or other reasons." 33 F.3d at 1090 n.1, 1097.

The Ninth Circuit went on to hold that under such circumstances, even though Pantron's representations were literally true, they were "deceptive" and should be enjoined as false advertising under the FTCA. 33 F.3d at 1097.

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[1] The Ninth Circuit acknowledged that "*the evidence makes clear that the Helsinki Formula does work* to some extent to combat baldness in some people some of the time." 33 F.3d at 1099 (emphasis added).

In making the factual finding that the Helsinki Formula's efficacy stemmed solely from the "placebo effect," the Ninth Circuit decided to disbelieve the testimony of Pantron's expert, Dr. Schreck-Purola, who the trial court expressly found to be "credible." (Findings of Fact, ¶ 12.) Dr. Schreck-Purola testified at trial that the efficacy of the Helsinki Formula was *not* due to the placebo effect, but rather that its active ingredients "help alleviate baldness by destroying the cholesterol in the testosterone that destroys hair follicles." 33 F.3d at 1093.

The Court of Appeals also rejected the expert testimony of Dr. Annik Pons, a dermatologist at one of the foremost hospitals in Paris and a member of several French and international societies in the field of dermatology. 33 F.3d at 1098-99. Dr. Pons testified that, based on medical studies she conducted, the ingredients of the Helsinki Formula were very effective at decreasing hair loss and had some positive effect on growing hair.

Having rejected the testimony of Drs. Schreck-Purola and Pons, the Court of Appeals decided instead to credit both:

(1) The testimony of the FTC's expert, Dr. Ganiats, who the district court disbelieved, and to whom the district court referred as "unjustifiably arrogant on the stand" and subject to a "vigorous and damaging cross-examination illuminating his lack of knowledge about many details in the study [he conducted]" (Memorandum of Opinion and Intended Judgment, p. 6); and

(2) A study conducted by the same Dr. Ganiats, which the trial court found to be filled

with "serious defects." (Findings of Fact, ¶ 16.)

The Ninth Circuit further decided that the district court was wrong in refusing to award restitution or disgorgement of profits and *ordered that the district court had no choice but to order Pantron to disgorge its profits and pay restitution to its satisfied customers.* 33 F.3d at 1103. The Ninth Circuit additionally held that the district court erred in refusing to hold Lederman personally liable for monetary relief. *Id.*

REASONS FOR GRANTING THE WRIT

1. The Ninth Circuit Has Misinterpreted The FTCA To Create A New Category Of False Advertisement That Prohibits Truthful Advertising To Satisfied Customers.

Judge Reinhardt begins his opinion by stating that it is "deciding a previously unresolved question of federal consumer protection law." 33 F.3d at 1090. In fact, what the Ninth Circuit does is to expand radically what constitutes a "false advertisement" under the FTCA, by creating a totally new category of false advertisement that prohibits *truthful* statements in advertising made to satisfied customers.

The Ninth Circuit's creation of a new type of false advertising is utterly inconsistent with the FTCA and its stated objective: *to protect consumers.* Rather than protecting consumers, the Ninth Circuit has expanded the statute to hinder manufacturers from advertising products that work and that satisfy their customers.

In order to require the district court to enjoin Pantron's advertisements of its product's efficacy, the Ninth Circuit had no choice but to create a new category of false advertisement, *because under the traditional interpretation of the statute, the FTC failed to prove false advertising.* It has always been the rule that where, as here, the FTC bases its FTCA claim on a false representation of efficacy,[2] the burden falls on the FTC to prove that the representation made is false. The Ninth Circuit acknowledges this, stating that "the government must carry the burden of proving that the express or implied message conveyed by the ad is false." 33 F.3d at 1096, *quoting, In re Thompson Medical Co.*, 104 F.T.C. 648, 818-19 (1984).

In this case, there is no dispute that the message conveyed by Pantron is that the "Helsinki Formula is effective to arrest hair loss and promote regrowth." 33 F.3d at 1095. For the FTC to have proven that such a message is false, the FTC had to show *that the Helsinki Formula is not effective.* Even under the Ninth Circuit's view of the facts, *the FTC failed to carry that burden.* The Ninth Circuit concedes that there was sufficient evidence in the record to support the district court's finding that

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[2] There are two theories the FTC can assert in a false advertising case involving objective product claims. The FTC can assert – as they did here – the "falsity" theory, that is, that a representation was made that is false. 33 F.3d at 1096. In the alternative, the FTC can rely on the "reasonable basis" theory, that is, that the advertisement lacked a reasonable basis for asserting that the message was true. *Id.* The Ninth Circuit noted that the FTC "clearly and expressly abandoned the reasonable basis theory, both in the district court and [the Court of Appeals]." *Id.*

"use of the Helsinki Formula might arrest hair loss in some of the people some of the time" and "the Helsinki Formula does work to some extent to combat baldness." 33 F.3d at 1097, 1099. *Therefore, under the normal interpretation of the FTCA, Pantron's advertising of efficacy is clearly not false.*

Unable to bar Pantron's advertising based on the traditional interpretation of the statute, Judge Reinhardt decides to fashion "out of whole cloth" an entirely new category of "false advertising" under the FTCA. Specifically, the Ninth Circuit holds that even if a product is effective as advertised, the advertisement is deceptive if that efficacy is *solely* based on the "placebo effect." 33 F.3d at 1100.

As discussed in Section 2 below, the Court of Appeals' conclusion that the Helsinki Formula's efficacy is based solely on the placebo effect is contrary to the trial court's finding and much of the evidence in the record, and is based on an inappropriate shift of the burden of proof to Pantron. But even assuming, *arguendo*, that the Court of Appeals' factual finding is correct, the creation of a new category of false advertising that precludes such representations is not supported by case law, plainly inconsistent with the purpose of the FTCA, and unjustified by any public policy.

As an initial matter, it should be emphasized that the Ninth Circuit has created here a *totally new* category of false advertising under the FTCA. *No other court* has interpreted the FTCA to create such a category.

Furthermore, nothing in the statute supports such an interpretation. Section 55 of the FTCA defines "false

advertisement" as an advertisement that is "misleading in a material respect." 15 U.S.C. § 55(a)(1). Nothing in Pantron's advertisements about efficacy is misleading: such advertisements state that the Helsinki Formula works and *even the Ninth Circuit concedes that to be true.* Consumers are getting *precisely what they were promised.*

Furthermore, such an interpretation is utterly inconsistent with the stated purpose of the FTCA, that is, "to protect the consumer." *Natural Petroleum Refiners Ass'n v. F.T.C.*, 482 F.2d 672, 685 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951 (1974). *See also Regina Corp. v. F.T.C.*, 322 F.2d 765, 768 (3d Cir. 1963) ("The purpose of the Federal Trade Commission Act is to protect the public").

No consumer is being protected by the Ninth Circuit's actions here. The evidence is undisputed that the consumers of the Helsinki Formula are satisfied with the product's efficacy. They do not believe they are being cheated, and, indeed, *the FTC could not find even one dissatisfied consumer to testify at trial.* It seems a foolish waste of government money – and surely not the intent of Congress in enacting the FTCA – to have the FTC trying to shut down companies that are selling products that are effective and that *consumers want to buy.*

In addition, consumers are not being harmed by using the Helsinki Formula: it is undisputed that the Helsinki Formula poses no health or safety risk. This is not like the situation where a cancer patient is "fooled" into taking a worthless substance and foregoes a drug that might save his or her life. In such a case, it might make sense for the FTC to step in, because consumers are risking their lives. The Helsinki Formula is a hair loss

product, not a cancer drug. Consumers suffer no danger by continued use of the product.

The only party who benefits from the Ninth Circuit's ruling is Upjohn, Pantron's competitor who convinced the FTC to bring this action in the first place, because its own federal action against Pantron was unsuccessful. But the FTCA was not enacted to protect competitors; it was enacted to protect *consumers*. Consumers do not need protection from a product that works and with which they are satisfied.

Therefore, the Ninth Circuit clearly erred in creating a new category of false advertising and its order must be reversed.

2. The Ninth Circuit Without Any Case Or Statutory Support Places The Burden On The Advertiser To Exclude The Possibility That Its Product's Efficacy Is Solely The Result Of The "Placebo Effect" And Restricts The Evidence Which May Be Relied Upon In Attempting To Meet That Burden.

Not only has the Ninth Circuit created a new category of false advertising, it has also mistakenly shifted the burden of proof to Pantron and unjustifiably restricted the type of evidence a party can introduce to prove that its product is effective as advertised.

Admittedly, Judge Reinhardt does not specifically state that he has shifted the burden of proof; but that is in reality what he has done. In his opinion, Judge Reinhardt justifies his reversal of the trial court's judgment by stating that "*[a]ll* of the evidence of effectiveness adduced by

Pantron can be explained by the placebo effect." 33 F.3d at 1097 (emphasis in original). What that statement reveals is that the Court of Appeals has mistakenly put the burden of proof on Pantron to exclude the possibility that the efficacy of the Helsinki Formula is solely the result of the placebo effect.

Indeed, the only evidence the FTC proffered on the issue of the efficacy of the Helsinki Formula was the testimony of their experts, each an American scientist who never bothered to test the Helsinki Formula. Nonetheless, each felt competent to opine that they saw *no reason to believe* that the Helsinki Formula would work and, therefore, any efficacy of the Helsinki Formula *must have been* the result of the placebo effect. Such testimony is clearly inconsistent with the FTC's burden to prove falsity. It would be one thing if the FTC's experts had tested the Helsinki Formula and concluded that it did not work; it is quite another to have a few doctors say that they see no reason why it *does* work. The FTC's burden is to prove that the Helsinki Formula does not work, not that its paid skeptics cannot figure out why it does.

Furthermore, the Ninth Circuit holds that, in proving a product's efficacy, a party may rely only on "evidence developed under accepted standards of scientific research." 33 F.3d at 1097. In effect, what the Ninth Circuit means by this is that a defendant can prove efficacy *only* by standards acceptable to the *American medical community*. There is no conceivable justification for this xenophobic evidentiary restriction.

As with the creation of a new category of false advertisement, the Ninth Circuit offers no case citation to support such a proposition, and that is because there is no such case. This is yet another new requirement the Ninth Circuit has decided to engraft upon the FTCA.

Furthermore, there is no policy reason to support a new evidentiary restriction prohibiting an advertiser from proving efficacy by anything other than "scientific evidence." Here, Pantron submitted unrefuted testimony of customers who stated that the product worked for them and a consumer satisfaction survey showing that this was a common belief among customers in general. If the purpose behind the FTCA is to protect consumers and consumers are happy with a product as advertised, *why is the FTC getting involved at all?*

Furthermore, such an argument is totally contrary to the purpose of the FTCA: to protect consumers, not to protect American scientists who are threatened by anything they do not develop themselves. If consumers are satisfied with a product as advertised (and are not suffering any adverse health effect), it should make no difference what such scientists think.

Moreover, it is highly insulting to the American public for the FTC to argue, as it does here and as the Court of Appeals in essence acknowledges, that consumers are *too stupid* to know what is good for them and incapable of determining whether their hair is growing or whether their hair loss is decreasing. It should be left to the trier

of fact to determine the weight to be given such evidence.[3]

Finally, Pantron did submit several Western European medical studies (performed consistent with the standard of the countries in which they were conducted) and the testimony of two eminent European scientists, all of which support the claim that the Helsinki Formula is inherently effective. The district court found the studies to "solidly support[ ]" the efficacy of Pantron's product. (Findings of Fact, ¶ 10.) The Court of Appeals, however, rejected them all as inconsistent with *American* standards for such studies. 33 F.3d at 1098-99.

There is no reason to apply the different American standards here. Again, there is no health or safety risk. If there were, it makes sense that products must be proven safe by the strictest of standards. To the contrary, at issue here is a hair loss product, and, as noted by the district court, "[t]he consequences of error are less than cataclysmic, both to society and the individual." (Conclusions of Law, ¶ 8.)

Requiring the highest standards of scientific proof in order to advertise a hair loss product is the height of

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[3] Thus, the trial court here found:

> [W]ho's to say that a balding gentleman in his idle years who comes forward and testifies fervently that his pate is become younger than he because of [Helsinki Formula] is simply deluding himself?

(Memorandum of Opinion and Intended Judgment, at p. 3.)

The Court further found that "[i]t is hard to believe that such witnesses cannot tell whether the product works and are simply deluding themselves." (Findings of Fact, ¶ 13.)

regulatory overkill. There is no justification for this heightened evidentiary scrutiny and the Court of Appeals' decision should be reversed.

3. The Ninth Circuit Erred In Holding – In Contrast To The Decisions Of Other Circuits – That A District Court Is Mandated, And Has No Discretion To Refuse, To Award Restitution And Disgorgement Of Profits Under The FTCA.

It would be bad enough if Judge Reinhardt had merely prohibited Pantron from making efficacy claims that are supported in the record. But the Ninth Circuit went a step further and, in contrast to the decisions of other circuits, mandated the district court to require Pantron to make restitution (to its satisfied customers) and disgorge its profits, all of which, if the FTC has its way, *could total millions of dollars*. The Ninth Circuit is simply wrong, as a matter of law, in holding that a district court has no discretion to decide whether or not to award restitution or disgorgement of profits.

A district court's power to award restitution and consumer redress in connection with a violation of the FTCA is not explicitly addressed in the statute, but rather is part of the district court's broad and traditional equitable powers. *F.T.C. v. H.N. Singer, Inc.*, 668 F.2d 1107, 1113 (9th Cir. 1982). Even if a defendant's conduct in cases involving the FTCA falls within the category of conduct for which restitution *may* be awarded, no other court has ever held that the award of restitution and/or disgorgement of profits is mandatory and that the trial court has no discretion to refuse to award such relief.

Judge Reinhardt's opinion is in conflict with decisions of other circuits which have made clear that the award of restitution *is within the discretion of the trial court.* For example, the district court in *F.T.C. v. Kitco of Nevada, Inc.*, 612 F. Supp. 1280 (D. Minn. 1985), made this point perfectly clear:

> [A]ny award of restitution or rescission is not mandatory but is within the court's discretion.

Id. at 1281, n.1. *See id.* at 1296 ("District courts have discretion to model orders to fit the exigencies of the particular case").[4]

The *Kitco* court relied on a Second Circuit opinion involving the award of restitution in actions brought by the SEC to enjoin violations of the securities laws. In that case, *SEC v. Commonwealth Chem. Securities, Inc.*, 574 F.2d 90, 96 (2d Cir. 1978), the Court held that in awarding restitution, "availability [of restitution] is entrusted to the discretion of the court."

Indeed, the very case cited by Judge Reinhardt to mandate the trial court to order monetary relief establishes that restitution is not a mandatory remedy. Thus, the Ninth Circuit opinion incorrectly cites *F.T.C. v. Amy Travel Service, Inc.*, 875 F.2d 564, 573 (7th Cir. 1989), *cert. denied*, 493 U.S. 954 (1990), for the proposition that a corporation *is automatically liable for restitution* if it made

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[4] *Kitco* is not alone in this holding. In *F.T.C. v. Security Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1316 (8th Cir. 1991), the Eighth Circuit held that consumer redress is a matter about which the trial court has "broad remedial discretion."

misrepresentations of a kind usually relied upon by reasonably prudent persons. 33 F.3d at 1102.

In fact, the *Amy Travel* case stands for a quite different proposition. First, the portion of *Amy Travel* cited by the Ninth Circuit relates to *individual*, rather than *corporate* liability. Second, and more important, contrary to Judge Reinhardt's recitation of its holding, the *Amy Travel* case holds that under the circumstances where a misrepresentation is of a kind usually relied upon by reasonably prudent consumers and consumer injury results, restitution "may" – not must or should – be ordered:

> An individual *may* be held liable under the FTCA for corporate practices if the FTC first can prove the corporate practices were misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and that consumer injury resulted.

875 F.2d at 573 (emphasis added). In support of this proposition, the *Amy Travel* court cites *Kitco, the very case which, as noted above, holds that the award of restitution is not mandatory. Id.*

One further case should be discussed as well, for it too is in conflict with the Ninth Circuit's decision here. Neither in the opinion nor in the FTC's appellate briefs is there any citation to any case where a Court of Appeals has reversed a trial court's refusal to grant monetary relief under the FTCA. Pantron has found one such case and it is instructive. In *F.T.C. v. Southwest Sunsites, Inc.*, 665 F.2d 711 (5th Cir.), *cert. denied*, 456 U.S. 973 (1982), the Fifth Circuit reversed the trial court's refusal to grant a preliminary injunction freezing the defendant's assets and notifying consumers of misrepresentations. The

Court of Appeals held – as does the Ninth Circuit here – that the trial court applied the wrong legal standard. *Id.* at 722-23.

The Court of Appeals did not, however, mandate that the trial court freeze the defendant's assets and order consumer notification. Rather, in obvious recognition of the trial court's discretion in the matter, the Court of Appeals remanded for the trial court to reconsider using the proper legal standard. *Id.*

That, of course, is precisely what should have been done here. The district court here should be given the opportunity to exercise its discretion as to whether restitution is appropriate based on the correct legal standard. As noted, a district court's decision to award restitution is a two-step process. First, the district court must determine whether there has been false advertising, whether the misrepresentations made are of a type reasonably relied on by consumers, and whether consumer injury resulted. Second, if all those factors apply, the district court has *the broad discretion* to decide whether or not to award restitution.

The district court here never had the opportunity to engage in the second step of the analysis. Based on factual findings and legal conclusions (found incorrect by the Ninth Circuit), the district court found that no injury to consumers had occurred (33 F.3d at 1102) and, accordingly, restitution could not as a matter of law be awarded. Now that the Ninth Circuit has decided that consumers did suffer actual injury (33 F.3d at 1102), the district court should be given the opportunity to reach the second step of the analysis: *should it exercise its broad discretion to*

award restitution. The Court of Appeals has broad powers, but not the power to overrule the discretion of the district court *before that discretion is even exercised*.

4. Disgorgement Of Profits And Restitution Is Inappropriate In A Case Where Consumers Are Satisfied And The Record Reflects That The Product Advertised Is Effective.

Even aside from the issue of whether the Court of Appeals has improperly removed discretion from the trial court, the award of any restitution or disgorgement of profits in this case is completely contrary to the intent and purpose of the FTCA.

It is incomprehensible that the FTCA could have been intended to require a business to make restitution and disgorge profits made in the sale of a product *to satisfied consumers*. Consumers here do not want restitution: they want to continue to buy the product that has been working for them for years.

Nor does monetary relief make sense in light of the Ninth Circuit's agreement that there is evidence in the record supporting the trial court's finding that the Helsinki Formula is effective. Admittedly, the Ninth Circuit believes that efficacy is solely due to the placebo effect. But even were that the case, customers have still purchased a product *that works* (for whatever reason). Pantron supplied precisely what was advertised, and restitution or disgorgement of profits is utterly inappropriate.

CONCLUSION

For the foregoing reasons, Pantron requests that this petition for certiorari be granted.

Dated: February 28, 1995

BROWNE & WOODS
EDWARD A. WOODS
ALLEN B. GRODSKY
Attorneys for Petitioners
Pantron I Corporation and
Hal Z. Lederman

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant-Cross-Appellee,

v.

PANTRON I CORPORATION, et al.,
Defendants-Appellees-Cross-Appellants.

Nos. 92-56228, 92-56292.

United States Court of Appeals,
Ninth Circuit.

Argued and Submitted Feb. 3, 1994.

Decided Aug. 25, 1994.

Federal Trade Commission (FTC) brought action against seller of hair loss product alleging that representations as to product's efficacy constituted false advertisement under Federal Trade Commission Act. The United States District Court for the Central District of California, Richard A. Gadbois, Jr., J., entered injunction barring seller from making representations that scientific evidence established that product was effective, but allowed seller to represent that product was subject of medical investigative work by responsible European physicians and that product was effective to some extent for some people, and refused to order monetary equitable relief. Cross-appeals were taken. The Court of Appeals, Reinhardt, Circuit Judge, held that: (1) advertisement regarding efficacy of hair loss formula constituted false advertisement; (2) seller was required to pay restitution to consumers or to disgorge profits; (3) district court abused its discretion in refusing to hold corporation's president and sole owner personally liable for monetary relief; (4) fact that district court's conclusion that hair loss product was a drug was not essential to outcome of

action did not require Court of Appeals to strike conclusion; (5) hair loss product was "drug" within meaning of Federal Trade Commission Act; and (6) seller was not entitled to award of sanctions.

Affirmed in part, reversed in part and remanded.

Melvin H. Orlans, F.T.C., Washington, DC, for plaintiff-appellant-cross-appellee.

Allen B. Grodsky, Browne & Woods, Beverly Hills, CA, for defendants-appellees-cross-appellants.

Appeal from the United States District Court for the Central District of California.

Before: D.W. NELSON, REINHARDT, and BRUNETTI, Circuit Judges.

REINHARDT, Circuit Judge:

These consolidated appeals require us to decide a previously unresolved question of federal consumer protection law: Whether it is lawful for a seller to represent a product as "effective" when its efficacy results solely from a "placebo effect."[1] We conclude that the answer is no and that the representation constitutes a "false advertisement" under the Federal Trade Commission Act.

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[1] The term "placebo effect" refers to the fact that even a product of no inherent merit whatsoever will often have some degree of effectiveness in treating the condition for which it is employed, for psychological or other reasons. For example, a patient who ingests sugar pills while believing they are strong pain relievers may well experience some pain relief, even though sugar pills are themselves inherently worthless in treating pain. In this example, the sugar pill is a "placebo" and the relief experienced by the patient is the "placebo effect."

The Federal Trade Commission, Pantron I Corporation, and Hal Z. Lederman appeal separate parts of the district court's order which enjoined Pantron and Lederman (Pantron's president and sole owner) from making certain advertising representations regarding the effectiveness of a purported baldness cure which Pantron markets as "The Helsinki Formula." In its appeal, the F.T.C. claims that the district court erred by not also enjoining Pantron and Lederman from representing that: (1) the Formula "was the subject of medical investigative work by responsible European physicians," and (2) the Formula "is effective to some extent for some people in dealing with male pattern baldness." The F.T.C. also argues that the district court erred in refusing to grant monetary equitable relief. In their cross-appeal, Pantron and Lederman argue that the district court erred in concluding that the Formula is a "drug" under 15 U.S.C. § 55(c). They also ask for sanctions. We reverse the district court's judgment to the extent that the F.T.C.'s appeal challenges it. However, we affirm the district court on the issues raised in the cross-appeal.

I.

Pantron I Corporation and Hal Z. Lederman market a product known as the Helsinki Formula.[2] This product supposedly arrests hair loss and stimulates hair regrowth in baldness sufferers. The Formula consists of a conditioner and a shampoo, and it sells at a list price of $49.95

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[2] Except where there is a special reason to differentiate the two, the remainder of our opinion will refer to Pantron and Lederman collectively as "Pantron."

for a three-month supply. The ingredients which allegedly cause the advertised effects are polysorbate 60 and polysorbate 80.[3] Pantron offers a full money-back guarantee for those who are not satisfied with the product.

This case involves the F.T.C.'s challenge to Pantron's advertisements promoting the Helsinki Formula. These advertisements (including late-night infomercials hosted by the "Man from U.N.C.L.E.," Robert Vaughn) feature both the hair loss claim and the claim that the Formula promotes growth of new hair in baldness sufferers. They also represent that recognized scientific studies support these claims. As occasionally occurs in our administrative state, Pantron's advertising claims came under rather intense scrutiny from a variety of regulatory entities. After the United States Postal Service,[4] the Food and

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[3] The complete ingredient listing for the shampoo is: purified water, olefinsulfate, cocamidopropyl betaine, amino oxide, glycerine, chamomile extract, aloe vera gel, allatonin, D-panthenol, propylene glycol, jojoba oil, wheat germ oil, PABA, Vitamins A, D, and E, biotin, polysorbate 80, nucleic acids (RNA-DNA), folic acid, keratin protein, polyquaterium 10, citric acid, imidozolidinyl urea, and fragrance.

The complete ingredient listing for the conditioner is: water, polysorbate 80, polysorbate 60, biotin, propylene glycol, imidozolidinyl urea, niacin, and fragrance.

[4] The Postal Service filed an administrative complaint against Pantron in February of 1987, which alleged that Pantron was making false claims regarding the Formula's effectiveness in preventing hair loss and promoting hair regrowth. As a result of this action, Pantron and the Postal Service entered into a consent order that prohibited Pantron from making such claims when selling their products through the mail unless the claims were supported by reliable scientific evidence.

Drug Administration,[5] the Los Angeles County District Attorney,[6] and even the Council of Better Business Bureaus[7] took varying degrees of action against Pantron's advertising and marketing of the Formula, the Federal Trade Commission filed the instant suit on November 18, 1988. The F.T.C.'s complaint directed itself to the advertisements which represented that the Helsinki Formula was effective and that there was scientific support for this conclusion. The complaint alleged that the representations were false and constituted an unfair or deceptive trade practice in violation of sections 5 and 12 of the Federal Trade Commission Act. *See* 15 U.S.C. §§ 45, 52. The Commission sought a permanent injunction and monetary equitable relief.

The district court conducted a 5-day bench trial in November of 1989. The F.T.C. presented a variety of evidence which tended to show that the Helsinki Formula had no effectiveness (other than its placebo effect) in

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[5] An F.D.A. agent inspected Pantron's facilities in June of 1987. Two months later, the F.D.A. sent Pantron a "Notice of Adverse Findings," which stated that the agency was unaware of competent scientific evidence to support the efficacy claims made on the Helsinki Formula's labels.

[6] In July of 1987, the D.A.'s office executed a search warrant on Pantron's facilities and alleged, in the probable cause affidavit, that Pantron's claims that the Helsinki Formula would promote hair growth were false.

[7] In October of 1988, the National Advertising Division of the Council of Better Business Bureaus sent Pantron a letter stating that the studies on which the company relied for its efficacy claims had not been properly conducted. It requested that Pantron cease claiming that the Helsinki Formula is effective in preventing hair loss and promoting hair regrowth.

arresting hair loss or promoting hair regrowth. The Commission introduced the expert testimony of Dr. Karl Kramer, a dermatologist who stated that, based on his knowledge and review of the medical literature, there was "no reason to believe" that the Helsinki Formula would be in any way useful in treating hair loss. He also stated that his opinion was in accord with the consensus view of the medical community.

Dr. Kramer's testimony was corroborated by two other experts, Drs. Elaine Orenberg and Theodore Ganiats. Dr. Orenberg stated that the studies on which Pantron relied – by Dr. Schreck-Purola and Dr. Pons – failed to satisfy the generally-accepted scientific standards of being randomized, double-blinded, and placebo controlled. Dr. Ganiats, who had conducted a study of another polysorbate-60-based baldness treatment, expressed his opinion that neither polysorbate-60 nor polysorbate-80 – the two allegedly result-producing ingredients in the Helsinki Formula – was effective in reducing hair loss or promoting hair regrowth.[8] The court

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[8] He explained his conclusion with the following statement:

> When you start with the fact there's no reason to believe that either drug would work, and you add to that the fact that one drug has been shown not to work, it's very damning evidence for the whole family.

He further elaborated:

> We have a condition before the study that it is unlikely that polysorbates were effective. It's unlikely because we can't imagine a reasonable mechanism of action. If we would have had a positive study, it would have had to have been confirmed, because it

also took judicial notice that the Food and Drug Administration had issued a rule that prohibited marketers of over-the-counter baldness treatments from labelling their products as effective. *See* 21 C.F.R. § 310.527. The F.D.A.'s final rule, which applies to *all* over-the-counter hair growth products, specifically identifies polysorbate 60 and several other ingredients which are found in the Helsinki Formula. *See id.* § 310.527(a). The F.D.A. rule concludes that "[b]ased on evidence currently available, all labeling claims for OTC hair grower and hair loss prevention drug products for external use are either false, misleading, or unsupported by scientific data." *Id.*[9]

Finally, the F.T.C. introduced evidence of two studies which had determined that polysorbate-based products were ineffective in stopping hair loss and promoting hair

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still would have been unlikely. But a negative study, given the pre-study possibility of it being effective was very low, coupled that with a negative study makes it incredibl[y] unlikely.

[9] The F.T.C. also brought to the district court's attention two other district court cases and a U.S. Postal Service decision which had all determined that polysorbate-based products produced by other manufacturers were ineffective in reducing hair loss and promoting hair regrowth. *See F.T.C. v. California Pacific Research*, 1991-2 Trade Cas. (CCH) ¶ 69,564, 1991 WL 208470 (D.Nev.1991); *F.T.C. v. Intra-Medic Formulations*, No. 85-2819 (S.D.Fla. Feb. 25, 1986); *In re New Generation*, U.S.P.S. Dkt. No. 11/152 (May 13, 1983) *vacated sub nom. California Pacific Research v. United States Postal Serv.*, Civ. No. R-83-172 (BRT) (D.Nev. Jan. 10, 1985), *rev'd*, 794 F.2d 682 (table) (9th Cir.1986), *cert. denied*, 479 U.S. 986, 107 S.Ct. 577, 93 L.Ed.2d 580 (1986). These decisions had reviewed essentially the same studies as were introduced into evidence in the present case, but Pantron was not a party to any of them.

regrowth. The more important study, known as the Groveman study, was a placebo-controlled, double-blinded, randomized study which was published in the *Archives of Internal Medicine*, a peer-reviewed journal. *See* Howard D. Groveman, et al., *Lack of Efficacy of Polysorbate 60 in the Treatment of Male Pattern Baldness*, 145 Archives of Internal Medicine 1454 (1985). This study found "[n]o statistically significant difference" between the control and treatment groups, and that nearly a quarter of the participants in each group reported new hair growth. The authors concluded that "polysorbate 60 is not an effective remedy for MPB [male pattern baldness]," and that hair regrowth products possess a very strong placebo effect.[10] In addition, the F.T.C. introduced the so-called Shuster study, an unpublished study which compared a polysorbate-based product to Pantene, a hair product that was presumed to have no inherent curative or restorative qualities. This study also concluded that polysorbate-based products were ineffective, although the F.T.C.

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[10] Dr. Kramer stated that the Groveman study was "corroborating evidence" for his conclusion that the Helsinki Formula was not effective. Dr. Orenberg stated that the Groveman study (along with the Shuster study) was conducted according to the most scientifically appropriate criteria of any of the clinical studies on polysorbate-based products she had reviewed (including the Pons and Schreck-Purola studies). Dr. Ganiats, one of the doctors who conducted the Groveman study, testified that it was validly designed and performed for its objective. Finally, Dr. Donald Guthrie, the F.T.C.'s statistician, testified that the Groveman study "was a well-designed and well-executed study, generally following scientific principles you find in a good scientific study." He further stated that "the methodology of the study was quite good," and that "from the statistical standpoint it seems quite competently done."

acknowledges that "the failure to include a clearcut placebo somewhat reduces [its] value."[11]

In response, Pantron introduced evidence that users of the Helsinki Formula were satisfied that it was effective. It offered the live and deposition testimony of 18 users who had experienced hair regrowth or a reduction in hair loss after using the Formula. It also introduced evidence of a "consumer satisfaction survey" it conducted in late 1988. In this "survey," which occurred during routine sales follow-up calls, a representative of Pantron interviewed a cross-section of 579 Helsinki Formula customers. Although the Pantron official who conducted the survey could not remember the questions he asked, and the company did not keep a record of these questions, Pantron introduced the results of its "survey" into evidence. The survey data showed positive results in a significant percentage of users, ranging from 29.4% of those who had used the product less than 2 months, to 70% of those who had used it for 6 months or more. Pantron also introduced evidence that over half of its orders come from repeat purchasers, that it had received very few written complaints, and that very few of Pantron's customers (less than 3%) had exercised their rights under the money-back guarantee.

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[11] Notwithstanding the lack of a clear placebo, Dr. Kramer testified that the Shuster study was a "well-designed scientifically-controlled study" and that, if one accepts the inference that Pantene is without inherent curative or restorative qualities, the study "lends some support to the proposition that the polysorbates do not work in male pattern baldness." Dr. Orenberg testified that the Shuster study closely approximated the proper scientific standards.

Pantron also introduced several clinical studies of its own. First, it offered the results of Finnish studies, for which the Helsinki Formula was named, performed by Dr. Ilona Schreck-Purola. Her uncontrolled, unblinded, unrandomized, un-peer-reviewed study concluded that a polysorbate-based product was effective in arresting excessive hair loss within two to four weeks, and that it led to new hair growth in 60% of the subjects within four months. Although Dr. Schreck-Purola acknowledged that "the medical community remains of the opinion that polysorbates are not effective in treating male pattern baldness,"[12] she nonetheless stated that, in her opinion, polysorbates help alleviate baldness by destroying the cholesterol in the testosterone that destroys hair follicles.

Pantron also introduced the testimony of Dr. Annik Pons, a French dermatologist who conducted an uncontrolled, unblinded study of a polysorbate product's effectiveness. This study relied on two measures of hair loss. First, participants were to count the number of hairs which fell in their sink or on their pillow each day. Second, the participants received three examinations by physicians who, applying the same amount of pressure each time, pulled a tuft of hair from the participant's scalp and counted the number of hairs pulled out.[13]

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[12] Both Drs. Kramer and Orenberg testified that the Schreck-Purola study (as well as the Pons study; *see infra*) was scientifically invalid because it lacked a placebo control and was not reproducible because it lacked a standardized way of measuring the hair. They testified that the studies did not provide a proper basis to conclude that polysorbate-based products would be effective in alleviating male pattern baldness.

[13] Dr. Kramer testified that these measurements were "sort of haphazardly done," and therefore the study was not reproducible.

Employing this method, the doctors found an 82-87% decrease in the rate of hair loss in eleven months. The physicians sought to measure *new* hair growth as well; using a magnifying device to count new hairs, they found new hair growth in up to 35% of the participants within three months. Based on these results, Dr. Pons testified that a polysorbate-based product was effective.[14]

Finally, Pantron introduced the testimony of Dr. Paul Williams. Dr. Williams, a statistician, testified that the Groveman study was invalid because its sample size (68 men received polysorbate 60 and 73 men received a placebo) was inadequate. He stated that there was a 40% chance that the Groveman experiment would falsely conclude that an effective product is ineffective. He estimated that a minimum of 151 subjects in each group would be necessary for the study's conclusions to be reliable.[15]

On September 24, 1991, the district court issued findings of fact and conclusions of law. It found that Pantron had made the representations of efficacy and scientific support that the F.T.C. had alleged. Turning to the question whether these representations were false, the district court determined that "[t]here is no evidence in the

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[14] Pantron also introduced evidence of an uncontrolled, unblinded study by a Dr. Marie, which was conducted in France on 46 male subjects at about the same time Dr. Pons conducted her study. This study, which used substantially the same methodology as the Pons study, found a substantial decrease in hair loss, as well as new hair in 30 of the 46 subjects.

[15] As noted above, the F.T.C. offered the testimony of its own statistician, Dr. Guthrie, to rebut Dr. William's testimony.

record to support a contention that the Helsinki Formula is wholly ineffective." The district court found that the studies and anecdotal evidence offered by Pantron "support[ed] the proposition that the compound works for some people some of the time."[16] Thus, it concluded that the F.T.C. had failed to carry its burden of showing that Pantron made a false claim when it represented that the Helsinki Formula was effective.

However, the district court found "no scientifically valid evidence that polysorbate 60 *is* effective for treatment of hair loss or for inducing growth." Thus, the district court concluded that the F.T.C. had "marginally carried its burden on the charge of falsity in defendant's claims of scientific proof." Accordingly, it entered an injunction, which barred Pantron and Lederman from making any express or explicit representations that scientific evidence establishes that the Helsinki Formula "is effective in any way in the treatment of baldness or hair loss." However, the order specifically allowed the defendants to

> state that the Helsinki Formula (or a product similar thereto) was the subject of medical investigative work by responsible European physicians, if such statement is accompanied by clear and conspicuous disclosure that the work

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[16] In another part of its decision, the district court phrased its finding as follows: "the Helsinki Formula most probably works some of the time for a lot of people." With respect to the issues raised on this appeal, there is no significant difference between these two statements, and we treat them interchangeably.

> did not conform to recognized standards in the United States for medical/scientific studies.

Another provision of the injunction prohibited "any misrepresentation . . . regarding the effectiveness of such product or program in the treatment of baldness," but it allowed Pantron and Lederman to

> state that the Helsinki Formula is effective to some extent for some people in dealing with male pattern baldness, if such statement is accompanied by clear and conspicuous disclosure that the product's effectiveness (1) is more likely to involve arrest of hair loss than growth of new hair, and (2) is not explained or supported by scientific studies recognized under standards in use in the United States.

The court refused to order monetary equitable relief, because it concluded that "[t]he F.T.C. has not established that defendants' conduct caused actual deception and injury to consumers, nor that defendant Lederman knew or should have known such conduct was fraudulent."[17]

The F.T.C. appeals from the district court's refusal to award broader injunctive relief and any monetary equitable relief. Pantron cross-appeals from the district court's conclusion that the Helsinki Formula is a "drug" for purposes of 15 U.S.C. § 55(c).

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[17] In its order for judgment, the district court added an additional conclusion of law: "The Helsinki Formula is a drug within the meaning of 15 U.S.C. Section 55(c)."

II.

The F.T.C. challenges the portions of the injunction which allow Pantron and Lederman to make representations regarding the effectiveness of and support among responsible European physicians for the Helsinki Formula.[18] It argues that the district court clearly erred in finding that there was "no evidence . . . to support a contention that the Helsinki Formula is wholly ineffective," and in finding that "the Helsinki Formula most probably works some of the time for a lot of people." The Commission also claims that the district court applied an incorrect legal standard in evaluating the evidence of effectiveness. We agree that the district court used an erroneous legal standard and hold that the parts of the order challenged by the F.T.C. must be modified.

A.

The Federal Trade Commission brought this suit pursuant to sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52. Section 5(a) of the Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce" and empowers the Commission to prevent such acts or practices. 15 U.S.C. § 45(a)(1) & (2). Section 12 of the Act is specifically directed to false advertising. That section prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, or cosmetics." 15 U.S.C. § 52(a)(2). It also provides that the dissemination of any

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[18] In their cross-appeal, Pantron and Lederman do not challenge any part of the district court's injunction.

such false advertisement is an "unfair or deceptive act or practice in or affecting commerce" within the meaning of section 5. 15 U.S.C. § 52(b). The Act defines "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect." 15 U.S.C. § 55.

In its own adjudications, the F.T.C. has to some extent clarified the legal standards which apply in section 12 cases. In *Cliffdale Assocs.*, 103 F.T.C. 110 (1984), the Commission announced a three-part test for determining whether an advertisement is misleading and deceptive in violation of section 12. Under this test,

> the Commission will find an act or practice deceptive if, first, there is a representation, omission, or practice that, second, is likely to mislead consumers acting reasonably under the circumstances, and third, the representation, omission, or practice is material.

Id. at 164-65. The Commission has consistently adhered to the *Cliffdale Associates* standard. *See, e.g., Figgie Int'l*, 107 F.T.C. 313 (1986); *Thompson Medical Co.*, 104 F.T.C. 648 (1984). Although we have not heretofore explicitly adopted the test, we have stated that "[t]he new standard became binding on the F.T.C. when it was adopted in *Cliffdale Associates.*" *Southwest Sunsites, Inc., v. F.T.C.*, 785 F.2d 1431, 1435 n.2 (9th Cir.), *cert. denied*, 479 U.S. 828, 107 S.Ct. 109, 93 L.Ed.2d 58 (1986). *See also Kraft, Inc. v. F.T.C.*,970 F.2d 311, 314 (7th Cir. 1992) (setting forth the *Cliffdale Associates* test in slightly edited form), *cert. denied*, ___ U.S. ___, 113 S.Ct. 1254, 122 L.Ed.2d 652 (1993). As we previously suggested in *Southwest Sunsites*, we believe that the general outlines of the *Cliffdale Associates*

test set forth the appropriate general principles for determining whether advertising is deceptive. Except as noted below, *see infra* nn. 20-21, we adopt that standard.

In this case, there is no question that Pantron represented that the Helsinki Formula was effective. The district court found that the advertisements "contain claims (a) that the Helsinki Formula is effective to arrest hair loss and promote regrowth, and (b) that the product's efficacy is demonstrated by responsible and recognized scientific studies." Pantron does not challenge this finding on appeal. There is also no question that these claims are material. Express product claims are presumed to be material,[19] and Pantron does not assert that its representations were immaterial.[20] Therefore, the only question before us is whether Pantron's representations regarding the product's effectiveness were likely to deceive or mislead consumers.[21]

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[19] *See Thompson Medical Co.*, 104 F.T.C. at 816; *F.T.C. Policy Statement on Deception*, Oct. 14, 1983 (hereinafter "*Policy Statement*"), *reprinted in Cliffdale Associates*, 103 F.T.C. at 174, 182.

[20] Accordingly, we need not decide whether a representation must be "likely to affect [consumers'] choice of, or conduct regarding, a product" in order to be "material" under section 15, *Cliffdale*, 103 F.T.C. at 165, or whether the statute encompasses the misrepresentation of "any fact that is important to consumers." *Id.* at 188 (Pertschuk, Commissioner, concurring in part and dissenting in part).

[21] In addition, because this case involves *express* objective product claims, we do not consider whether these claims are "so far-fetched that reasonable consumers would not believe [them]." *Thompson Medical*, 104 F.T.C. at 788 – 89 n.6. Thus, we do not decide whether section 12 requires "that an act or practice be considered from the perspective of a 'consumer acting

There are a number of ways in which a representation, omission, or practice can mislead consumers within the meaning of section 12.[22] In particular, the Commission has identified two theories on which the government can and often does rely in section 12 cases involving objective product claims. First, the government can assert a so-called "falsity" theory. To prevail on such a theory, the government must "carry the burden of proving that the express or implied message conveyed by the ad is false." *Thompson Medical*, 104 F.T.C. at 818-19. Alternatively, the government can rely on a so-called "reasonable basis" theory. To prevail on this theory, the government must "show that the advertiser lacked a reasonable basis for asserting that the message was true." *Id.* at 819. In determining whether an advertiser has satisfied the reasonable basis requirement, the Commission or court must first determine what level of substantiation

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reasonably under the circumstances,' " *Cliffdale*, 103 F.T.C. at 165, or whether it "requires only that a substantial number of consumers could be misled." *Id.* at 187 (Pertschuk, Commissioner, concurring in part and dissenting in part).

[22] The *Policy Statement* provides the following non-exclusive list:

> Practices that have been found misleading or deceptive in specific cases include false oral or written representations, misleading price claims, sales of hazardous or systematically defective products or services without adequate disclosures, failure to disclose information regarding pyramid sales, use of bait and switch techniques, failure to perform promised services, and failure to meet warranty obligations.

Reprinted in Cliffdale, 103 F.T.C. 174, 175. In addition, the *Policy Statement* noted that "[a]dvertising that lacks a reasonable basis is also deceptive." *Id.* n. 5.

the advertiser is required to have for his advertising claims. Then, the adjudicator must determine whether the advertiser possessed that level of substantiation.

Although the district court conducted both a "falsity" and a "reasonable basis" analysis, the F.T.C. clearly and expressly abandoned the reasonable basis theory, both in the district court and in this court.[23] Accordingly, we discuss only the falsity theory.

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[23] This abandonment is puzzling, to say the least, because it is difficult to imagine how the Commission could fail to prevail on a reasonable basis theory. Application of the factors set forth in *Thompson Medical*, 104 F.T.C. at 821, would appear to compel the conclusion that Pantron should be required to possess some controlled clinical evidence that the Helsinki Formula is effective. This conclusion stems from the nature of the product claims, *see Porter & Dietsch, Inc.*, 90 F.T.C. 770, 885 (1977) (stating that claims that any food, drug, or device can help a user achieve any result, such as weight loss, require "competent scientific or medical tests or studies"), *aff'd*, 605 F.2d 294 (7th Cir.1979), *cert. denied*, 445 U.S. 950, 100 S.Ct. 1597, 63 L.Ed.2d 784 (1980), the fact that the placebo effect makes it "difficult or impossible for consumers to evaluate by themselves" the truth of these claims, *Thompson Medical*, 104 F.T.C. at 822, the economic harm consumers suffer if the advertisement is false, *see id.* at 824-25 (requiring two controlled clinical tests because a false claim would be "economically harmful to consumers," despite its finding that any health risk was "minimal"), and the fact that "experts in the field would agree" that it is reasonable to require at least one (and possibly more than one) controlled clinical test. *Id.* at 821. As we explain *infra*, the record appears to make it clear that Pantron cannot meet even that minimal requirement. However, in view of the F.T.C.'s representations at trial and on appeal, we do not base our decision in whole or in part on a failure to meet the reasonable basis requirement.

B.

The district court concluded that the F.T.C. failed to carry its burden of proving that Pantron's efficacy representations were false. It held that "[t]o prevail on its charge that defendant has misrepresented the efficacy of the 'Helsinki Formula,' the F.T.C. must prove that the product is wholly ineffective; *i.e.*, that it does not work at all." The district court held that the F.T.C. had not satisfied its burden of proof. It concluded that, although Pantron's clinical studies did not conform to contemporary American scientific standards, they nevertheless showed that the Formula is effective in reducing hair loss in many people.

We hold that the district court erred in concluding that Pantron's representations regarding the Helsinki Formula's efficacy did not amount to false advertising. Although there was sufficient evidence in the record to support the district court's finding that use of the Helsinki Formula might arrest hair loss in some of the people some of the time, the overwhelming weight of the proof at trial made clear that any effectiveness is due solely to the product's placebo effect. As we explain *infra*, we conclude that a claim of product effectiveness is "false" for purposes of section 12 of the Federal Trade Commission Act if evidence developed under accepted standards of scientific research demonstrates that the product has no force beyond its placebo effect.

As Drs. Kramer, Orenberg, and Ganiats testified, the consensus of the medical and scientific community is that polysorbate-based products have no effectiveness beyond their placebo effect in combatting male pattern baldness.

See supra pages 1091-92. Even Dr. Schreck-Purola acknowledged that the medical community had reached such a conclusion. It has done so because it has found *no* credible theory explaining how these products work. As Dr. Ganiats explained, when, as in the case of the Helsinki Formula, "we can't imagine a reasonable mechanism of action," responsible scientists cannot conclude that the product is effective absent very strong evidence coming from well-designed studies. *See supra* note 8.[24] Dr. Kramer echoed this view, stating that "the standards to which you are held when one is testing an unorthodox theory really have to be quite rigid."[25]

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[24] Drs. Kramer, Orenberg, and Ganiats all implicitly or explicitly rejected Dr. Schreck-Purola's theory that the Helsinki Formula works by destroying the cholesterol in the testosterone which kills hair follicles. Dr. Kramer came the closest to accepting this theory when, under cross-examination, he stated that Dr. Schreck-Purola's proposed mechanism was "an interesting theory" which might conceivably affect the progress of male pattern baldness. Yet Dr. Kramer clearly found this theory unworthy of reliance – based on his knowledge and review of the literature, he saw "no reason to believe" that the Helsinki Formula would be effective in any way. *See supra* page 1092.

[25] By contrast, a study can corroborate an accepted scientific theory without being held to the strictest standards. Thus, the Groveman study, which was placebo-controlled, double-blinded, randomized, and published in a peer-reviewed journal, corroborates the consensus of medical opinion as described by the F.T.C.'s experts, even if it was not perfect in its design. The district court gave two significant reasons for disregarding this study: that it did not test "the precise formula marketed as the Helsinki Formula" and that it "probably did not involve a sufficient number of subjects." As to the first criticism, it applies as well to Pantron's studies on which the district court relied. The Pons study, like the Groveman study, involved polysorbate 60

Yet Pantron did not present any evidence which rebutted the consensus of the medical community that polysorbate-based products such as the Helsinki Formula are inherently ineffective. *All* of the evidence of effectiveness adduced by Pantron can be explained by the placebo effect. Dr. Kramer offered uncontradicted testimony that hair growth studies reflect the existence of a very high placebo effect, as high as 41% in one study.[26] Moreover, this placebo effect has an objective as well as a subjective component: not only do parties to the study misperceive hair growth, but patients will on occasion experience actual, measurable hair growth despite the fact that they have used a product of no intrinsic worth. Although the reasons for this objective placebo effect are unclear, the testimony presented in the district court indicated that a likely explanation is the stimulation of the scalp which comes from massaging *any* product, including plain water, into the head on a regular basis.

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but not polysorbate 80, and Dr. Schreck-Purola had previously stated in court documents that the Helsinki Formula did *not* contain the formula she studied. As for the second criticism, it is inconsistent with the district court's treatment of Pantron's studies. The district court found that Pantron's studies "solidly supported" the conclusion that the Formula is effective for some people "irrespective of certain 'state-of-the-art' scientific deficiencies in that work." Yet the court heard unrebutted testimony that whatever the flaws of the Groveman study, it was far more reliable and consistent with scientific standards that Pantron's French and Finnish studies.

[26] Drs. Pons, Schreck-Purola, and Williams all agreed that there is a substantial placebo effect.

None of Pantron's evidence of effectiveness takes the placebo effect into account. Pantron's evidence of consumer satisfaction is the most obviously flawed. The substantial placebo effect indicates that consumers simply cannot tell whether over-the-counter baldness cures are effective, inherently or otherwise. This is especially true in light of the irregular procession of hair loss – what an individual reports as the product's effectiveness in arresting hair loss may simply be the natural course of baldness. Much of Pantron's "consumer satisfaction" evidence is suspect on other grounds as well. Pantron's so-called "consumer satisfaction survey" was conducted by its own sales staff "as we did our follow ups to offer additional product." No record of the questions was kept. In addition, Pantron's low refund rate may not represent satisfaction. As Dr. Andreasen testified, even dissatisfied consumers may fail to exercise their right to a refund, because they think it not worth the trouble, because they feel guilty for having been deceived, because they credit the product's ineffectiveness to their own failure to follow instructions, or for any one of a number of other reasons.

Similarly, Pantron's clinical studies – and the expert testimony which relied solely on these studies – simply failed to account for the placebo effect. It is undisputed that these studies were not placebo-controlled. Pantron argues, however, that despite the lack of placebo controls, these studies were valid measures of the Helsinki Formula's effectiveness. First, it argues that Dr. Schreck-Purola's tests involved scalp biopsies which eliminated all subjectivity in the measurement of hair loss. Yet, because the study was neither controlled nor blinded, it

could not account for the naturally irregular course of hair loss, nor for biased observation. Most significantly, it could not account for the *objective* aspect of the placebo effect.

Pantron also argues that "the French and Finnish studies were controlled by 'historical controls.' " The company contends that, because the participants in the study had previously tried many other remedies without success, the lack of results the participants had achieved in the past served as a control. Yet the designs of these studies never explicitly incorporated "historical controls," and they did not make a detailed comparison of the polysorbate-based products's results with the results the participants had achieved previously.[27] Finally, Dr. Kramer offered unrefuted testimony that historical controls are especially poorly suited for hair loss studies because of the irregular progression of male pattern baldness.

Finally, Pantron relies on Dr. Schreck-Purola's testimony that the success rate in the Schreck-Purola and Pons studies was too high to be explained by the placebo effect. Although the Rogaine studies showed a placebo effect of only 30-40%, the Schreck-Purola study showed hair growth in 60% of the subjects, and the Pons study

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[27] The one exception is the Pons study, which did collect some data on the products previously used by the participants and the results previously obtained. However, as Dr. Kramer testified, this study suffered from significant flaws in its research design, such as heavy reliance on self-reporting, division of the study subjects among too many investigating physicians, and lack of reproducibility.

showed hair growth in 80% of the subjects. Yet as Pantron's statistical expert conceded, it is improper to compare placebo rates across different studies, because "the placebo effect . . . is entirely dependent upon the experimental design and the people doing the evaluation and the protocol that's been established." Absent a true control, Pantron's studies simply do not rebut the clinical and other scientific evidence presented by the F.T.C., which clearly demonstrates that any effectiveness of the Helsinki Formula arises solely from the placebo effect.[28]

C.

Assessing this evidence, the district court concluded that the F.T.C. had failed to carry its burden of showing that the Helsinki Formula is "wholly ineffective." In essence, the district court held that, as a matter of law, a seller can represent that its product is effective even when this effectiveness is based solely on the placebo effect. We believe that the district court misapprehended the law.

As an initial matter, we should explain that we reject the argument vigorously urged by the F.T.C., that the

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[28] Because of the strong placebo effect, and the fact that it has an objective component, absent a controlled study design a physician who actually tests a product such as the Helsinki Formula will be in no better position to determine whether the product is effective than one who merely reviews the studies. Thus, the district court should not have discounted the F.T.C.'s expert testimony on the ground that the Commission's experts had not personally tested the Helsinki Formula. In any event, none of Pantron's experts had tested the precise formula the company sells, either. *See supra note* 25.

district court clearly erred as a factual matter in determining that "the Helsinki Formula most probably works some of the time for a lot of people." The Commission argues that this finding is inconsistent with another finding made by the district court, that there was "no scientifically valid evidence that polysorbate 60 *is* effective for treatment of hair loss or for inducing growth."[29] In essence, the F.T.C. urges that we should hold that contemporary standards of scientific evaluation – which preclude the consideration of the placebo effect – are the determinants of what is "true" and what is "false." In its view, when the application of these contemporary scientific standards would lead to the conclusion that a product is ineffective, any claim that the product is effective is "false" in an intrinsic, absolute sense. We disagree. Contemporary scientific standards obviously are not the definitive or sole measure of what is "true" or "false." Galileo's theories were contrary to then-contemporary scientific standards, but we treat as a given that these theories were as essentially "true" when he explained them as they surely are today. Moreover, depending on our terms of reference, it may well not be incorrect to say

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[29] The district court's use of the term "no scientifically valid evidence" referred, essentially, to the lack of properly-conducted, blinded, placebo-controlled clinical studies, as well as the fact that the consensus of scientific opinion holds that polysorbate-based products are ineffective aside from their placebo effect. When the finding of "no scientifically valid evidence" is read in this light, there is no conflict between this finding and the district court's finding that the Helsinki Formula is effective some of the time for some people – presumably because of the placebo effect.

that an efficacy representation is "true" when the product's effectiveness results solely from the placebo effect: for, in a certain sense, it would be "true" for a seller of sugar pills to represent that they relieve pain for some of the people some of the time, just as it would be "true" for Pantron to state that the Helsinki Formula sometimes arrests hair loss. Whether because of psychological factors or because of the physiological effects of regularly massaging *any* product into the scalp, the evidence makes clear that the Helsinki Formula does work to some extent to combat baldness in some people some of the time.

However, neither scientific standards on the one hand, nor the broadest possible definition of "truth" on the other, can determine what constitutes a "false advertisement" under section 12 of the Federal Trade Commission Act. Indeed, a "false advertisement" need not even be "false"; it need only be "misleading in a material respect." 15 U.S.C. § 55. We must read this definition of "false advertis[ing]" in light of the overriding purpose of the F.T.C. Act: "to protect the consumer from being misled by governing the conditions under which goods and services are advertised and sold to individual purchasers." *National Petroleum Refiners Assoc. v. F.T.C.*, 482 F.2d 672, 685 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951, 94 S.Ct. 1475, 39 L.Ed.2d 567 (1974); *see also supra* pages 1095-97 (discussing the *Cliffdale* test). The question we must face, then, is not whether Pantron's claims were "true" in some abstract epistemological sense, nor even whether they could conceivably be described as "true" in ordinary parlance. Rather, we must determine whether or not efficacy representations based solely on the placebo

effect are "misleading in a material respect," and hence prohibited as "false advertis[ing]" under the Act.

Taking account of these principles, we hold that the Federal Trade Commission is not required to prove that a product is "wholly ineffective" in order to carry its burden of showing that the seller's representations of product efficacy are "false." Where, as here, a product's effectiveness arises solely as a result of the placebo effect, a representation that the product is effective constitutes a "false advertisement" even though some consumers may experience positive results. In such circumstances, the efficacy claim "is 'misleading' because the [product] is not *inherently* effective, its results being attributable to the psychosomatic effect produced by the advertising and marketing of the [product]," *United States v. An Article . . . Acu-Dot . . .* , 483 F.Supp. 1311, 1315 (N.D.Ohio 1980), as well as (in cases such as this one) the objective effects caused by the use of *any* product or even non-product in treating the condition in question. The Court in *Acu-Dot* considered a magnetic patch, which the manufacturer had represented as effective in relieving muscle and joint pain. It concluded that "any therapeutic value of the [patch] is the result of its placebo effect," *id.* at 1314, and accordingly held that the manufacturer's representations were "misleading" under 21 U.S.C. § 352(a). In reasoning which fully applies to section 12 of the Federal Trade Commission Act, the court noted that "[a] kiss from mother on the affected area would serve just as well to relieve pain, if mother's kisses were marketed as effectively as the Acu-Dot device," *id.* at 1315, and that a consumer purchasing a pain-reliever would expect it to have more therapeutic value than such a kiss.

The *Acu-Dot* court's reasoning is persuasive here. Under the evidence in the record before us, it appears that massaging vegetable oil on one's head would likely produce the same positive results as using the Helsinki Formula. All that might be required would be for Wesson Oil to remove Florence Henderson as its flack and substitute infomercials with Mr. Vaughn that promote its product as a baldness cure. As the Commission has explained, the purposes of section 12 of the F.T.C. Act dictate that a court should not allow a seller to rely on such a placebo effect in supporting a claim of effectiveness:

> "The Commission cannot accept as proof of a product's efficacy a psychological reaction stemming from a belief which, to a substantial degree, was caused by respondent's deceptions." Indeed, were we to hold otherwise, advertisers would be encouraged to foist unsubstantiated claims on an unsuspecting public in the hope that consumers would believe the ads and the claims would be self-fulfilling.

Bristol-Myers Co., 102 F.T.C. 21, 336 (1983).[30] Moreover, allowing advertisers to rely on the placebo effect would not only harm those individuals who were deceived; it would create a substantial economic cost as well, by allowing sellers to fleece large numbers of consumers who, unable to evaluate the efficacy of an inherently

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[30] The F.D.A. has at least implicitly determined that the placebo effect may not be used to support a claim of effectiveness, since it has determined that "all labeling claims for OTC hair grower and hair loss products for external use are either false, misleading, or unsupported by scientific data," 21 C.F.R. § 310.528(a), despite the evident placebo effect of these products.

useless product, make repeat purchases of that product. *See Thompson Medical*, 104 F.T.C. at 718 (initial decision).[31]

The evidence before the district court made clear that there is no reason to believe that the Helsinki Formula is at all effective outside of its placebo effect. Accordingly, it was materially "misleading" under *Cliffdale Associates* for Pantron to represent that the Formula is effective in combatting male pattern baldness. We "resist[] the impulse to allow [Pantron] to market a product that works only by means of a placebo effect on the basis that it nevertheless often achieves a [result] as claimed." *Acu-Dot*, 483 F.Supp. at 1315. Rather, we conclude that the district court erred in deciding that the F.T.C. had not shown that Pantron's effectiveness claims were false.

In light of our conclusion, we instruct the district court to remove the portion of its injunction which allowed Pantron to "state that the Helsinki Formula is effective to some extent for some people." Such a representation – which, on the record before us, rests solely on

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[31] Pantron relies on only one case for the proposition that it may advertise a product as effective based only on its placebo effect. Yet this case, *F.T.C. v. Simeon Management Corp.*, 391 F.Supp. 697 (N.D.Cal.1975), *aff'd*, 532 F.2d 708 (9th Cir.1976), does not stand for this proposition. In *Simeon Management*, the district court denied a preliminary injunction to prevent a weight loss clinic from advertising that its program included the use of a certain prescription drug which was itself ineffective. The district court concluded that, because the program as a whole had been proven effective through clinical studies, there was no need to enjoin the use of the drug. Here, unlike in *Simeon Management*, the overwhelming weight of the evidence shows that Pantron's entire hair-growth program is ineffective, and that it consists solely of using the ineffective product.

the placebo effect – is misleading for the reasons set forth above. Moreover, we believe that the misleading nature of this statement is not cured by the district court's requirement that such a representation "be accompanied by clear and conspicuous disclosure that the product's effectiveness (1) is more likely to involve arrest of hair loss than growth of new hair, and (2) is not explained or supported by scientific studies recognized under standards in use in the United States." The first of these limitations does not in any way detract from Pantron's claim – which, on the record before us, is "false" as a matter of law – that the Helsinki Formula is effective. It merely provides a more precise prediction of the manner in which the product will have its purportedly positive effects. As to the second limitation, it fails to provide full and fair information to the consumer and is therefore itself misleading. Scientific studies recognized under standards in use in the United States do not merely fail to explain or support Pantron's effectiveness claims; on the record before us, it is clear that they *refute* these claims and demonstrate that the Helsinki Formula has no effectiveness aside from its placebo effect. On remand, the district court shall modify its injunction to prohibit the company from making *any* representations that the Helsinki Formula is effective in arresting hair loss or promoting hair regrowth.

The district court shall also eliminate that portion of its current injunction which allows Pantron to "state that the Helsinki Formula (or a product similar thereto) was the subject of medical investigative work by responsible European physicians." In the context of an advertisement, such a statement carries the message that responsible

scientific studies demonstrate that the Formula is effective. This statement is materially misleading. To be sure, the district court required the statement to be "accompanied by clear and conspicuous disclosure that the work did not conform to recognized standards in the United States for medical/scientific studies." However, we believe that this proviso, like the other proviso added by the district court, does not resolve the problem it seeks to address. A representation that responsible European studies demonstrate the Helsinki Formula's effectiveness is misleading not merely because these studies did not conform to United States scientific standards, but because all available evidence developed under the far higher American standards demonstrates the *opposite* of the European studies: that the Helsinki Formula is *in*effective aside from its placebo effect. Pantron may not rely on the European studies in its advertisements, unless it discloses all facts necessary to ensure that the use of the study results is not misleading. If it wishes to cite the European studies, Pantron must disclose, at a minimum: (1) that recognized standards of medical and scientific experimentation in the United States are stricter than those under which the European studies were performed; (2) that researchers employing recognized American standards have studied the effectiveness of polysorbate-based hair growth products like the Helsinki Formula; and (3) that the unanimous conclusion of these researchers is that the Helsinki Formula and other similar products have no inherent curative or restorative effect.

III.

The F.T.C. argues that the district court erred in refusing to order Pantron or Lederman to pay restitution to consumers or disgorge their profits. Because the district court's refusal to award monetary equitable relief was based on the application of erroneous legal principles, we reverse.[32] We conclude that an application of the correct legal principles requires the district court to order monetary relief in this case, especially in light of our conclusion, set forth in the previous Part, that the F.T.C. fully proved its falsity case.

A.

Section 13(b) of the Federal Trade Commission Act provides "[t]hat in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction." 15 U.S.C. § 53(b). This provision gives the federal courts broad authority to fashion appropriate remedies for violations of the Act. As we explained in *F.T.C. v. H.N. Singer, Inc.*, 668 F.2d 1107 (9th Cir.1982), the authority granted by section 13(b) is not limited to the power to issue an injunction; rather, it includes the "authority to grant any ancillary relief necessary to accomplish complete justice." *Id.* at 1113. This power includes the power to order restitution. *See F.T.C. v. Amy Travel Serv., Inc.*, 875 F.2d 564, 571 (7th Cir.), *cert. denied*, 493 U.S. 954, 110 S.Ct. 366, 107 L.Ed.2d 352 (1989). A

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[32] A district court's grant of equitable relief is reviewed for abuse of discretion or the application of erroneous legal principles. *See Dexter v. Kirschner*, 984 F.2d 979, 982 (9th Cir.1992).

corporation is liable for monetary relief under section 13(b) if the F.T.C. shows that the corporation engaged in misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and that consumer injury resulted. *See id.* at 573.

Here, the district court concluded that Pantron had falsely claimed that the Helsinki Formula's effectiveness was supported by scientific proof. It also determined that these representations were material to consumers. Thus, the district court found the requisite material misrepresentations. Moreover, as we noted in the previous Part, Pantron's misrepresentations were even more extensive than the district court acknowledged.[33] In any event, the district court refused to order the company to pay restitution or disgorge its profits because it concluded that the F.T.C. had not established any actual injury to consumers. In particular, it relied on the fact that "[a]ny individual injuries have been only economic and only in amounts less than $100 – for which defendant had offered a reasonably adequate, albeit rarely exercised, remedy."

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[33] Pantron argues that the district court found that the F.T.C. failed to establish the first part of the controlling test, because the district court stated that the F.T.C. had not shown any "actual *deception* and injury" (emphasis added) and because the district court found that the product was an effective baldness remedy. However, the first part of the standard does not require *actual deception* but only misrepresentations of a kind reasonable people rely on. The district court clearly found all facts necessary to this requirement by finding that Pantron made misrepresentations regarding the scientific support for its efficacy claims and that these misrepresentations were material. Moreover, the district court's refusal to find any actual deception cannot stand in light of our conclusion in Part II, *supra*.

The district court's reasons for denying monetary equitable relief were inadequate as a matter of law. First, the district court erred when it relied on the fact that the consumer injuries have been only economic in nature. It is simply improper to treat this fact as a factor weighing against an award of monetary relief. The remedy of restitution seeks to correct unjust enrichment, and is therefore particularly suited to remedying economic injuries. Moreover, a major purpose of the Federal Trade Commission Act is to protect consumers from economic injuries. It would pervert the purposes of both the restitutionary remedy and the Act to deny monetary relief simply because the injury inflicted by the defendant is only economic in nature.

Second, the district court erred when it concluded that the modest amount of injury suffered by each individual consumer could preclude an order of restitution or disgorgement. Both the Commission and the courts have recognized that consumer injury is substantial when it is the aggregate of many small individual injuries. *See Orkin Exterminating Co. v. F.T.C.*, 849 F.2d 1354, 1365 (11th Cir.1988) ("As the Commission noted, although the actual injury to individual customers may be small on an annual basis, this does not mean that such injury is not 'substantial.' "), *cert. denied*, 488 U.S. 1041, 109 S.Ct. 865, 102 L.Ed.2d 989 (1989). As the F.T.C. rightly observes, to allow a district court to deny monetary relief on this basis would preserve the unjust enrichment that a false advertiser has acquired and would do so simply because the advertiser has defrauded a large number of people for small individual amounts. Refusing to order monetary

relief on this basis serves no legitimate purpose and is contrary to the purposes of the Act.[34]

Finally, the existence of a money-back guarantee is insufficient reason as a matter of law to preclude a monetary remedy. As the Seventh Circuit recognized in *Montgomery Ward & Co. v. F.T.C.*, 379 F.2d 666 (7th Cir.1967), allowing a seller to rely on a money-back guarantee as a defense to section 12 charges "would make the false advertising prohibitions of the Act a nullity. Anything might then be advertised as long as unsatisfied customers were returned their money." *Id.* at 671. For the same reasons, allowing such a guarantee to bar monetary relief would make the broad equitable remedial power in section 13(b) a nullity. Because even many unsatisfied customers will not take advantage of a money-back guarantee, a company which has engaged in consumer fraud would be able to retain a significant portion of the proceeds simply by making a largely illusory money-back offer.

Because the district court's refusal to order monetary relief against the corporation was based on the application of erroneous legal principles, and because an application of the proper principles compels an order of monetary relief, we instruct the district court to order the

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[34] Upon remand, the district court has the responsibility for tailoring the appropriate monetary relief. If the court reasonably concludes that it would be impossible or impracticable to locate and reimburse all of the consumers who have been injured by Pantron's misrepresentations, it may order some other remedy which requires Pantron to disgorge its unjust enrichment. Such an alternative remedy should provide direct benefits to consumers to the extent possible, however.

Pantron Corporation to pay monetary equitable relief to the extent of its unjust enrichment.

B.

We also conclude that the district court abused its discretion in refusing to hold Lederman *personally* liable for monetary relief. In making this decision, the district court reasoned that the F.T.C. had failed to establish that Lederman knew or should have known that Pantron's conduct was dishonest or fraudulent. The F.T.C., relying on traditional principles of equitable remedies, maintains that knowledge of deceptiveness should not be required for an order of restitution. We have not previously decided this question, and we need not do so here. The evidence is clear that Lederman's state of mind satisfied even the standard employed by those courts which require "knowledge." Those courts require the F.T.C. to show " 'actual knowledge of material misrepresentations, reckless indifference to the truth or falsity of such misrepresentations, or an awareness of a high probability of fraud along with an intentional avoidance of the truth.' " *Amy Travel Service*, 875 F.2d at 574 (quoting *F.T.C. v. Kitco of Nevada, Inc.*, 612 F.Supp. 1282, 1292 (D.Minn.1985)).

The evidence before the district court clearly established that Lederman acted with at least "reckless indifference to the truth or falsity" of Pantron's representations that scientific support existed for its efficacy claims. In 1982, he wrote to the F.D.A. to inquire about the reliability of the Schreck-Purola studies. The F.D.A. responded with a letter which stated that the

agency was unaware of any valid scientific evidence supporting the efficacy of over-the-counter baldness remedies. The agency also sent Lederman an article which related that the F.D.A.'s advisory panel had determined that such hair loss treatments are ineffective. Lederman received similar information from the F.D.A. after he requested assistance from his congressman in 1985. Moreover, even if these communications with the F.D.A. did not make him aware that a high probability existed that Pantron's representations regarding scientific support were false, Lederman certainly gained such an awareness from the Postal Service Proceedings against him and the company, the FDA's issuance of a "Notice of Adverse Findings," the search by the Los Angeles District Attorney, and the Better Business Bureau's determination that the studies on which Pantron relied were not properly designed or conducted. *See supra* notes 4-7 and accompanying text.[35]

There is no doubt from the record that Lederman was aware of a high likelihood that the company's claims of scientific support were false. Given the overwhelming

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[35] Lederman responds to these facts by stating that the district court found that he did not act dishonestly because it found that the Helsinki Formula was effective. However, the district court found that Pantron misrepresented the scientific support for its efficacy claims, and the evidence makes it apparent that Lederman had "knowledge" of the misrepresentation. That is all that is necessary for personal liability. Moreover, as we explained *supra*, the district court erred as a matter of law in concluding that the Helsinki Formula is effective. Accordingly, Lederman cannot rely on this conclusion to avoid personal liability.

evidence that no scientific support existed for the product's efficacy claims, Lederman could not have failed to know that the scientific support claims were false unless he intentionally avoided the truth. We therefore conclude that the district court erred in refusing to hold Lederman personally liable for monetary relief.

IV.

In its cross-appeal, Pantron argues that the district court's conclusion that the Helsinki Formula is a "drug" within the meaning of 15 U.S.C. § 55(c) should be reversed or stricken. Pantron contends that this conclusion was not necessary to the district court's decision and, in any event, that it was erroneous. We decline to disturb the district court's conclusion.

Pantron raises two arguments in its cross-appeal. First, it contends that we should strike the district court's conclusion that the Helsinki Formula is a "drug," simply because the conclusion was not essential to the outcome of the case.[36] Pantron cites no authority for the proposition that an appellate court may strike a district court's conclusion of law merely because it is dictum.[37] It simply

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[36] Pantron is incorrect when it states that the district court's resolution of this issue was *irrelevant* to the outcome. Section 12 of the F.T.C. Act, under which this action was brought, only applies to advertisements of "food, drugs, devices, or cosmetics." The district court's finding that the Helsinki Formula is a drug was relevant (although not necessary) to its determination that section 12 applied.

[37] We do not necessarily accept as correct Pantron's characterization of the district court's conclusion. We do so only ad

contends that "[t]he parties did not litigate whether the Helsinki Formula was a 'drug,' " and that it was therefore unfair or improper for the district court to decide the issue. While we might agree that a party could not be bound by a district court's finding on an issue which it did not have notice would be litigated, we conclude that Pantron was adequately informed that the question whether the Helsinki Formula was a "drug" would be contested. The pretrial order clearly identifies this question as one of the issues to be decided at trial. Although Pantron objected on the grounds that the question was unnecessary for decision of the case, it cannot claim that it did not receive notice that the question would be at issue. So long as the district court's conclusion that the Helsinki Formula is a "drug" has sufficient support in the record, therefore, we do not believe it appropriate to strike the conclusion simply because it is unnecessary to the district court's decision.

Pantron's second argument is that the district court erred on the merits in concluding that the product is a drug. We disagree. The company contends that the Helsinki Formula does not fit within the statutory definition of "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 15 U.S.C. § 55(c)(3). We see no error in the

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arguendo. The fact that a conclusion is not necessary does not in and of itself make it dictum. However, this is not the case in which to engage in a jurisprudential discussion of the meaning of the much-debated term "dictum." *See, e.g,* Charles W. Collier, *Precedent and Legal Authority: A Critical History,* 1988 Wis.L.Rev. 771.

district court's conclusion that the Helsinki Formula is intended to affect the bodily function of hair growth.

Pantron points to the labels on the Helsinki Formula (which identify the products only as a shampoo and a conditioner) and the television advertisements for the product (which state that it works by cleansing the tissues around the hair follicle and which also state that the Formula is "not a drug"). The company argues that these advertisements make clear that the product is not intended to affect the structure or functions of the human body. Pantron relies on *United States v. An Article of Drug*, 331 F.Supp. 912 (D.Md.1971), which held that Helene Curtis "Magic Secret" skin lotion, which produced a "temporary wrinkle-smoothing effect," *id.* at 915, was a cosmetic and not a drug. The "Magic Secret" court reached this conclusion despite the manufacturer's claims that the lotion smoothed away wrinkles and tightened the skin. Pantron seeks to analogize these claims with the representations it made regarding the Helsinki Formula.

However, the rule the "Magic Secret" court set forth supports rather than conflicts with our decision here. Application of the "Magic Secret" analysis dictates the conclusion that, unlike Helene Curtis's skin lotion, the Helsinki Formula is a drug. In holding that "Magic Secret" was a cosmetic and not a drug, the court reasoned that a consumer would interpret the manufacturer's advertisements as representing only that the product would cause a temporary, superficial change in the user's appearance. *See, e.g, id.* (quoting advertisements which represented that Magic Secret "smooths away wrinkles in minutes, keeps them away for hours"). The claims made by Pantron are far more than assertions that the Helsinki

Formula will alter the appearance of the user in a superficial way (such as stretching the skin to smooth away wrinkles) for a short period of time. They are representations that the product will cause the body to generate new hair in parts of the scalp where no hair currently exists. Such a claim is far more likely to be understood as affecting the structure or function of the body, and thus carrying "drug connotations," *id.*, than are Helene Curtis's representations regarding "Magic Secret." The district court did not err in determining that the Helsinki Formula is a "drug."

V.

Finally, Pantron urges that it be awarded double costs and attorneys' fees under F.R.A.P. 38. It claims that the F.T.C.'s appeal is frivolous because it merely seeks to overturn the district court's credibility findings. However, the Commission's position is clearly far from frivolous; as our disposition should suggest, we believe that the F.T.C.'s arguments clearly have merit. We find Pantron's action in seeking sanctions in this case to be wholly inappropriate. As we recently explained, "[s]anctions are an *extraordinary* remedy," which "will not be granted – nor should they be sought – as a matter of routine." *Martel v. County of Los Angeles*, 21 F.3d 940, 948 (9th Cir.1994) (emphasis added). Our admonition in *Martel* bears repeating here: "Parties who improperly seek sanctions, particularly repeat offenders, risk being subjected to sanctions themselves." *Id.*

VI.

The judgment of the district court is REVERSED in part and AFFIRMED in part. On remand, the district court is directed to modify the injunction as set forth in this opinion, and to order both Pantron and Lederman to pay monetary equitable relief.

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FEDERAL TRADE COMMISSION, Plaintiff/Appellant/ Cross-Appellee, v. PANTRON I CORPORATION, et al., Defendants/ Appellees/ Cross-Appellants.	Nos. 92-56228, 92-56292 D.C. No. CV 88-6696-RG **ORDER** (Filed Nov. 16, 1994)

Before: D.W. NELSON, REINHARDT, and BRUNETTI, Circuit Judges.

The panel has voted to deny Cross-Appellants' petition for rehearing and to reject the suggestion for rehearing en banc.

The full court has been advised of the en banc suggestion and no judge of the court has requested a vote on it.

The petition for rehearing is DENIED and the suggestion for rehearing en banc is REJECTED.

Edward A Woods, Esq.
BROWNE & WOODS
450 N. Roxbury Dr.
7th Floor
Beverly Hills, CA 90210

sw
92-56228

SERVICE LIST

Edward A. Woods. Esq.
Allen B. Grodsky, Esq.
Browne & Woods
Attorneys for Pantron I, Corp. and Hal Z. Lederman
450 North Roxbury Drive, Seventh Floor
Beverly Hills, California 90210

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION, Plaintiff, v. PANTRON I, CORP. and HAL Z. LEDERMAN, Defendants.	CASE NO. CV88-6696 RG(JRx) JUDGMENT (Filed July 22, 1992)

This action having come before the Court for non-jury trial on November 7, 14, 15, 16 and 21, 1989, and the Court having considered all the evidence and arguments presented and having entered Findings of Fact and Conclusions of Law in accordance therewith:

I

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that defendants, and each of them, and their officers, agents, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, offering for sale, sale or distribution of the Helsinki Formula or any other product or program

for the treatment or prevention of baldness or loss of hair, be and are hereby restrained and enjoined from:

(a) Representing directly or by implication, through advertisements, testimonials, endorsements or in any other manner, that scientific evidence establishes that such product or program relieves, cures, prevents or reverses the advance of baldness, or is effective in any way in the treatment of baldness or hair loss; *provided, however,* that defendant may state that the Helsinki Formula (or a product similar thereto) was the subject of medical investigative work by responsible European physicians, if such statement is accompanied by clear and conspicuous disclosure that the work did not conform to recognized standards in the United States for medical/scientific studies.

(b) Making any misrepresentation directly or by implication, through advertisements, testimonials, endorsements or in any other manner, regarding the effectiveness of such product or program in the treatment of baldness; *provided, however,* that defendants may state that the Helsinki Formula is effective to some extent for some people in dealing with male pattern baldness, if such statement is accompanied by clear and conspicuous disclosure that the product's effectiveness (1) is more likely to involve arrest of hair loss than growth of new hair, and (2) is not explained or supported by scientific studies recognized under standards in use in the United States.

II

IT IS FURTHER ORDERED that defendants shall:

(a) Promptly deliver a copy of this Judgment to each person (including agents, independent contractors and their employees) now or hereafter engaged in the advertising, sale or offering for sale of anti-baldness products for or on behalf of defendants, and secure forthwith from each such person a signed statement acknowledging receipt of the Judgment.

(b) Within thirty (30) days after service of this judgment upon defendants, file with the Court and serve on Commission counsel a sworn statement identifying the names, titles, addresses and telephone numbers of all persons to whom a copy of this Judgment has been delivered pursuant to paragraph II(a) of this Judgment.

(c) Preserve the following materials and make them available to Commission counsel or their designee upon request, for inspection and copying, for at least two years after creation or receipt (whichever occurs later) of the particular material:

1. all materials relied on in support of the representations covered by Part I of this Judgment,

2. all test reports, studies, surveys or other materials that tend to contradict, qualify or call into question any such representation or the supporting materials therefor,

3. all signed statements obtained pursuant to paragraph II(a) of this Judgment, and

4. all other business records necessary to assess defendants' compliance with this Judgment.

III

IT IS FURTHER ORDERED that the Court shall retain jurisdiction of this matter for all purposes.

/s/ Richard A. Gadbois, Jr.
RICHARD A. GADBOIS, JR.
United States
District Judge

DATED: July 22 1992

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION, Plaintiff, v. PANTRON I, CORP. and HAL Z. LEDERMAN, Defendants.	Civil No. 88-6696-RG (JRx) FINDINGS OF FACT AND CONCLUSIONS OF LAW

This matter was tried to the bench and argued by post-trial briefs. It stood submitted on February 26, 1990. The Court, having heard the testimony and examined the evidence and arguments offered by the parties, now makes its findings of fact and conclusions of law.

FINDINGS OF FACT

The following facts are found:

1. Defendant Pantron I, Corp. ("Pantron") is a California corporation that does business within the Central District of California in Los Angeles. Defendant Hal Z. Lederman is and has been the president and sole shareholder of defendant Pantron at all times.

2. Former defendants Pantron I, Corporation (a Nevada corporation) and Pantron III, Corp., were dismissed as parties to this litigation on July 17, 1989.

3. Defendant Pantron is engaged, directly and through agents and subcontractors, in the packaging,

advertising, offering for sale, sale and distribution of "Helsinki Formula" products. The Helsinki Formula products have been and are sold nationwide through means and methods chosen by defendant Lederman (or people who report to him), including advertising determined under his control and with his direct participation.

4. The Helsinki Formula is a topically applied non-prescription product for hair loss prevention and regrowth, sold as a three-month supply consisting primarily of a 4-ounce bottle of conditioner (scalp cleanser) and an 8-ounce bottle of shampoo. This package, which in some instances has included a bottle of supplementary vitamin pills and at various times during 1988 included a topically applied supplementary product called "the Accelerator," has been sold to consumers for $49.95 plus shipping and handling charges. The ingredients of the shampoo and conditioner (scalp cleanser) were determined by defendant Lederman, after consulting and obtaining input from others.

5. The ingredients of the Helsinki Formula shampoo, which is to be used daily, are: purified water, olefin-sulfate, cocamidopropyl betaine, amino oxide, glycerine, chamomile extract, aloe vera gel, allantoin, D-panthenol, propylene glycol, jojoba oil, wheat germ oil, PABA, Vitamins A, D and E, biotin, polysorbate 80, nucleic acids (RNA-DNA), folic acid, keratin protein, polyquaterium 10, citric acid, imidazolidinyl urea, and fragrance.

6. The ingredients of the Helsinki Formula conditioner (scalp cleanser), which is to be applied before and after shampooing and before retiring at night, are: water,

polysorbate 80, polysorbate 60, biotin, propylene glycol, imidozolidinyl urea, niacin, and fragrance.

7. Defendant Pantron causes advertisements of the Helsinki Formula to be broadcast on television in various states of the United States.

8. The Court's examination of defendant's advertisements establishes that they contain claims (a) that the Helsinki Formula is effective to arrest hair loss and promote regrowth, and (b) that the product's efficacy is demonstrated by responsible and recognized scientific studies. Both such claims are alleged by plaintiff to be false and deceptive, in violation of Sections 5(a)(1) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a)(1), 52.

9. Defendant's advertisements also contain an absolute money-back guarantee offer on the "Helsinki Formula," whereby anyone who requests a refund within 90 days of buying the product may get all his (or her) money back. Only two to three percent (2-3%) of Helsinki Formula purchasers have requested their money back.

10. There is no evidence in the record to support a contention that the Helsinki Formula is wholly ineffective. There is a fair amount of evidence to the effect that perhaps it should not be effective, or that if by chance it is effective no one can state precisely why, but in large measure the same may be said of minoxidil, the apparent male pattern baldness effect of which was discovered by pure chance rather than design. Some of the evidence on this issue was subjective and anecdotal but did support the proposition that the compound works for some people some of the time. That conclusion is solidly supported

by medical investigative work done by responsible physicians in Europe, irrespective of certain "state-of-the-art" scientific deficiencies in that work.

11. Some of the ingredients of the Helsinki Formula were analyzed in medical studies conducted in the early 1970's at the University of Helsinki in Finland by Dr. Ilona Shreck-Purola and Dr. Kai Setala. While studying skin cancer, Drs. Purola and Setala discovered that application of a solution containing polysorbate (among other things) to the skin of laboratory mice resulted in enhancement of hair growth. Subsequent clinical studies by Drs. Purola and Setala revealed that a formula containing polysorbate, niacin, biotin, amino acids, and other ingredients demonstrated positive hair growth in some subjects and stopped excessive hair loss in a larger number of subjects. The results of these studies were published, without peer review, by the University of Helsinki Department of Pathology.

12. Further studies by French physicians seemed to support the views of Dr. Purola, and a British photographic study of Helsinki Formula users also suggested its efficacy. The European studies were done by careful and experienced scientists working in good faith. Dr. Purola herself was a credible witness as to her observations and the work of others in Europe. The evidence did not show that she was acting for personal profit; she sold the European patent rights for a relative pittance and her relationships with American distributors, including defendants, have been less than munificently rewarding. Although neither the Finnish, French nor British studies pass muster under state-of-the-art scientific methods now

in use, they do establish that the Helsinki Formula most probably works some of the time for a lot of people.

13. That the Helsinki Formula is effective in some degree for a fair number of people is borne out by Pantron's user surveys. Defendant also produced consumer witnesses who testified that the Helsinki Formula worked for them. It is hard to believe that such witnesses cannot tell whether the product works and are simply deluding themselves. The FTC, on the other hand, did not present a single Helsinki Formula user to testify that the product had proved no more effective than any other shampoo in treating his (or her) hair loss.

14. The efficacy of the Helsinki Formula is more likely to be manifested in arrest of hair loss than in growth of new non-vellus hairs.

15. None of the FTC's experts ever tested or studied the Helsinki Formula to determine its efficacy in preventing hair loss or promoting new hair growth. Rather, they based their testimony that the Helsinki Formula is not effective almost exclusively on an article by Drs. Groveman, Ganiats, and Klauber entitled "Lack of Efficacy of Polysorbate 60 in the Treatment of Male Pattern Baldness" (the "Groveman study"), published in the peer-reviewed AMA Archives of Internal Medicine in August 1985, and the testimony of Dr. Karl Kramer.

16. The Groveman study does not establish the *ineffectiveness* of the Helsinki Formula. There are a number of serious defects in that study, not the least of which is that it did not test the precise formula marketed as the Helsinki Formula and probably did not involve a sufficient number of subjects. The study has apparently never

been cited in responsible professional literature and was not much enhanced by the testimony of Dr. Ganiats, who is not a dermatologist and lacked knowledge about many details of the study.

17. However, in light of current medical knowledge as to causes of balding and the theoretical action of the ingredient, there is no scientifically valid evidence that polysorbate 60 *is* effective for treatment of hair loss or for inducing growth.

18. Dr. Kramer testified that there is no recognized scientific basis for the proposition that polysorbate 60 or 80 will have an effect on male pattern baldness. In a rather wistful manner, Dr. Purola agreed that the medical community remains of the opinion that polysorbates are not effective in treating male pattern baldness.

19. Dr. Kramer has never done research on hair loss himself, never talked about it to anyone involved in this case, and acknowledged that he does not know as a fact that the Helsinki Formula is ineffective. However, his opinion is the best evidence in the record regarding the scientific acceptability of the studies defendant relies on.

20. The Court concludes, therefore, that the FTC has established by a bare preponderance of the evidence that defendant's claims to scientific proof of efficacy are unjustified in light of modern and accepted standards for research/analysis and scientific reporting.

21. As of the time of trial, defendant's latest advertisements, including newspaper ads, still contained the strong suggestion that medical science, through validly

performed and generally acceptable studies, supports its claim of efficacy for the Helsinki Formula.

22. There is no question but that defendant has marketed its product in good faith reliance on the Finnish, French and British studies and on anecdotal incidents reported by users of the "Helsinki Formula." Defendants had good reason, based on their own evidence, to resist the relentless governmental pressure to shut their business down.

23. There can be little doubt that the Upjohn Co., a competitor of Pantron's and a litigant against it in another court, whose attorneys attended these proceedings assiduously, was a prime mover in the FTC's action here.

24. There is no public safety or hazard issue in this case. No evidence was offered as to known or suspected side effects of the "Helsinki Formula."

25. The public as a whole has not been injured in any way by defendant's marketing of the "Helsinki Formula." Any individual injuries have been only economic and only in amounts less than $100 – for which defendant has offered a reasonably adequate, albeit rarely exercised, remedy.

26. To the extent the following conclusions of law may be deemed to include findings of fact, the facts are so found.

CONCLUSIONS OF LAW

1. The United States District Court for the Central District of California has jurisdiction over this matter

pursuant to 15 U.S.C. §§ 45(a) and 53(b) and 28 U.S.C. §§ 1331, 1337(a), and 1345.

2. Venue in this District is proper under 15 U.S.C. 53(b) and 28 U.S.C. § 1391(b), (c).

3. A sensible and perceptive view of the evidence by the trier of fact is all that is needed to determine whether the claims at issue are contained in defendant's advertisements.

4. In order to determine whether a permanent injunction should issue, the Court must first determine whether the plaintiff has succeeded on the merits; *i.e.*, met its burden of proof on either or both of its false advertising charges.

5. To prevail on its charge that defendant has misrepresented the efficacy of the "Helsinki Formula," the FTC must prove that the product is wholly ineffective; *i.e.*, that it does not work at all. The Court has concluded that the FTC has failed to carry that burden. Rather, the Helsinki Formula has been established to be effective in some degree for a fair number of people and the numbers of those people are great enough that defendant's efficacy claim, if clearly so stated, is not at all demonstrably false.

6. Anecdotal evidence, such as consumer testimony, cannot be relied upon in the strict scientific sense as a separate ground for conclusion regarding defendant's efficacy claims. However, the Court does not accept plaintiff's argument that satisfied consumers' experiences do not constitute valid proof of effectiveness, an argument grounded on manifestly distinguishable authorities arising in such very different procedural postures as FDA

drug certifications or administrative decisions on the merits, rather than false advertising charges in district court.

7. While not necessary to the Court's decision that plaintiff has not proven the falsity of defendant's efficacy claims, the "reasonable basis" analysis of *Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972), is helpful and relevant. Starting from the proposition that Section 5 of the FTC Act requires that an advertiser have a reasonable basis for any affirmative performance claim it makes for a product, the decision enumerates the following factors for analysis on a case-by-case basis to determine what constitutes a "reasonable" basis:

(a) the type and specificity of the claim made;

(b) the type of product;

(c) the possible consequences of a false claim;

(d) the degree of reliance by consumers on the claim; and

(e) the type and accessibility of evidence needed to form a reasonable basis for the claim.

8. Analysis of the *Pfizer* factors in this case reveals that defendant had a reasonable basis for claiming that the Helsinki Formula is effective for some people. Among other things, the efficacy claimed is cosmetic in nature. Purchasers' reliance on these claims is undoubtedly a blend of pious hope and healthy skepticism, and they can determine for themselves whether the Helsinki Formula has worked for them. The consequences of error are less than cataclysmic, both to society and the individual, as there is no risk of health or safety hazard, *see Thompson*

Medical Co., 104 F.T.C. 678, 822 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), *cert denied*, 479 U.S. 1086 (1987), and even if the product were ineffective consumers have not been at risk of losing their money because Pantron's guarantee has afforded them the opportunity to obtain a full refund of their purchase price, *see Jarvis v. Shackleton Inhaler Co.*, 136 F.2d 116, 120-21 (6th Cir. 1943). In these circumstances, the substantial quantum of evidence available to defendant was sufficient to support a "reasonable" belief in its efficacy claims for the "Helsinki Formula."

9. *Pfizer* recognizes that some advertising claims must be founded on "valid scientific or medical" bases. That principle undoubtedly applies to the scientific-support claims addressed below, *see Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 302 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980), but it is not at all applicable to efficacy claims unaccompanied by representations of scientific support.

10. The Court having found that the FTC has marginally carried its burden on the charge of falsity in defendant's claims of scientific proof, on the basis of Dr. Kramer's testimony that there is no recognized scientific basis for the proposition that polysorbate will affect male pattern baldness at all, and the claims being presumed in law to be material, those claims are necessarily deceptive and in violation of 15 U.S.C. §§ 45(a)(1) and 52. The irreparable injury necessary for issuance of an injunction against such claims must, under law, also be presumed. In absence of an injunction, defendant is likely to continue making such claims, and entry of a permanent injunction with respect thereto is in the public interest.

11. Here, there is no reason for disgorgement of profits or any other monetary relief. The FTC has not established that defendants' conduct caused actual deception and injury to consumers, nor that defendant Lederman knew or should have known such conduct was dishonest or fraudulent. *See FTC v. Amy Travel Service, Inc.*, 875 F.2d 564, 573-74 (7th Cir. 1989); *FTC v. International Diamond Corp.*, 1983-2 Trade Cases (CCH) ¶ 65,725 (N.D. Cal. 1983) at 69,705.

Dated: Sept. 24 1991.

/s/ Richard A. Gadbois, Jr.
Richard A. Gadbois
UNITED STATES
DISTRICT JUDGE

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION, Plaintiff, v. PANTRON I CORPORATION, a Nevada corporation; PANTRON I CORP. and PANTRON III CORP., California corporations; HAL Z. LEDERMAN, Defendants.	CASE NO. CV88-6696 RG(JRx) MEMORANDUM OF OPINION AND INTENDED JUDGMENT

A narrowly drawn judgment in this matter is ordered for the plaintiff.

This has been a difficult case on the issues and the merits, notwithstanding that it was handled at trial by counsel for both sides in a very professional and well-directed manner.

Somewhat simplistically stated the issues framed for trial were:

1. Did the defendants falsely claim that the Helsinki Formula ("HF") was effective as a remedy for hair loss and baldness?

2. Did the defendants falsely claim that HF's efficacy was solidly supported by valid and recognized medical/scientific studies?

3. In the event of an affirmative answer to either of the predicate questions what is the appropriate relief?

Claims

While the issue is not at all free of doubt the Court must conclude from its own view of them that defendants' advertising materials claim both efficacy and substantial scientific backing. The battle of experts here (e.g. Shimp v. Stewart) wasn't very helpful in that they predictably were in direct contradiction with the other. A sensible and perceptive view of the evidence is all that is needed here. What the Court's conclusion means to the parties will be different as to claims of efficacy and claims of scientific support.

Effectiveness

There is no evidence in the record supporting the contention that HF is wholly ineffective and, accordingly, the FTC fails of its burden of proof on this issue. There is a fair amount of evidence to the effect that perhaps it *should not* be effective, or that if by chance it is no one can tell you why, but in large measure the same may be said for minoxidil, the apparent MPB effect of which was discovered by pure chance rather than design. While the Finnish, French and British studies do not pass muster under state-of-the-art scientific methods now in use, they do establish that HF most probably works some of the time for a lot of people. This conclusion is also borne out by the defendants' user surveys. The European studies were done by careful and experienced scientists who

were working in good faith. Dr. Puıola herself was a credible witness as to her observations and the work of others in Europe. If she was in this for personal profit that is not at all apparent from the evidence. She sold the European patent rights for a relative pittance and her relations with American distributors, including defendants, have been less than munificently rewarding. As for anecdotal evidence, which cannot be relied on in the strict scientific sense as a separate ground for conclusion, who's to say that a balding gentleman in his middle years who comes forward and testifies fervently that his pate is become younger than he because of HF is simply deluding himself?[1]

The court must conclude that the FTC has not established that HF doesn't work at all; rather, HF has been established to be effective in some degree for a fair number of people and that the numbers of those people are great enough that the defendants' claim – if clearly so stated – is not at all demonstrably false. Fairness in advertising might require a clear distinction between efficacy as to arresting loss and efficacy as to growth of new non-vellus hairs, since the former would appear to be the more prevalent experience.

While not necessary to the court's decision that plaintiff has not proven the falsity of defendants' efficacy

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[1] Defendants were mercifully sparing of the court as to the quantum of direct anecdotal evidence at trial, although there was a great deal of indirect evidence on that issue. It is a fact, however, that the FTS [sic] apparently has never produced an HF user who would testify that the stuff was no more effective for him than "x" shampoo.

claim, the "reasonable basis" analysis of *Pfizer Inc.*, 81 F.T.C. 23, 64 (1972) is helpful and relevant. The Commission started from the proposition that fairness in advertising requires a reasonable basis for making an affirmative product claim. The decision establishes a number of criteria under which the fact-intensive analysis is made under this test.

Without going through the analysis in elaborate fashion it suffices to say that defendants had a reasonable basis to claim that HF was effective for some people. The type of claim is "efficacy" of a cosmetic nature – even though the formula may technically be a drug. There is no safety or hazard issue. The consequences of error in the claim are considerably less than cataclysmic to either society or any individual, and the degree of reliance by the normal consumer was undoubtedly a blend of pious hope and healthy skepticism. As discussed above there was available to defendants a substantial quantum of evidence to support reasonable belief.

Pfizer recognizes, of course, that some advertising claims must be founded on "valid scientific or medical" bases. That principle is undoubtedly applicable to the scientific support claim discussed below, but is not at all applicable to the efficacy claim here under analysis.[2]

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[2] The cases cited in Plaintiff's Reply argument at fn. 18 (*Weinberger*, etc.), are manifestly distinguishable from this case, principally – but not only – by reason of very different procedural postures in which the question was presented. The FTC elected to commence its proceeding in *this* court. This case is about a two-prong false advertising claim – not an FDA drug certification or review of any other administrative decision on the merits.

Scientific Support

The FTC has established by a bare preponderance of the evidence that defendants' claims to scientific proof of efficacy for HF are unjustified in light of modern and accepted standards for research/analysis and scientific reporting.

The principal fundaments upon which the FTC case on this issue rests are the Groveman study and the testimony of Dr. Kramer, as those are juxtaposed with the European studies and testimony of Dr. Purola. On that field of play the plaintiff squeaks out a late-game field goal victory.

The Groveman report is less than masterfully done for a number of reasons which the record will disclose – not the least of which is that it probably did not involve a sufficient number of subjects and did not test the precise formula here in issue. Its defects are defended on the quaint basis that the study is nonetheless scientifically sufficient to debunk defendants' claims.[3]

The Groveman study was also the subject of a battle of experts (Williams and Guthrie) who effectively cancelled each other out. That study was also not much enhanced by the testimony of Ganiats. He was unjustifiably arrogant on the stand, which no doubt triggered a vigorous and damaging cross-examination illuminating his lack of knowledge about many details in the study. He

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[3] This is only one of the several points rather tellingly made in Judge Thompson's order in *FTC v. California Research, etc.*, N-88-602 BRT, (D. Nev.) filed April 11, 1989. This court takes judicial notice of that opinion.

is not a dermatologist and the study has apparently never been cited in responsible professional literature. There is no question but that this study does not establish *ineffectiveness* of HF.

The FTC barely makes its case on this issue through Dr. Kramer's testimony. There is not question but that he is a brilliant physician – *summa* at Cornell in chemistry and first in his class at Johns Hopkins, with a *curriculum* the balance of which is equally illustrious. The substance of his testimony is that there is no recognized scientific basis for the proposition that polysorbate (he doesn't think a distinction between 60 and 80 is meaningful) will affect MPB at all. In a rather wistful manner Dr. Purola agrees. One wonders at the motives of Dr. Kramer in his testimonial peregrinations on this issue. Judge Thompson accurately described him as the "point man" in a "crusade against topical hair products," having an "animus" against their distributors. The first thing that comes to a skeptical mind is that he is an Upjohn hired gun.[4] That did not appear under cross-examination, and if there had been anything to it the able counsel for defense would have made sure we knew it.

While Dr. Kramer has never done research on hair loss himself and never talked to anyone involved in this case about it, and while he does not know as a fact that HF is ineffective, his opinion is the best we have in

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[4] There can be little doubt that Upjohn Co. has been *a* prime mover in all of this fuss. The Court believes that at least one lawyer for the minoxidil manufacturer was present at every single proceeding in this case spanning the better part of two years.

evidence. The requisite irreparable injury must, under law, be presumed.

Judgment

This Court will order a judgment consistent with the following:

1. The defendants have claimed in their advertising that (i) HF is effective as to both arrest of hair loss and hair regrowth and (ii) that effectiveness is demonstrated by responsible and recognized scientific studies.

2. The defendants' product, HF, is effective in dealing with MPB for some persons and to some extent, and they may not be enjoined from advertising that fact in careful fashion.*

3. HF was identified by and was the subject of medical investigative work done by certain responsible European physicians, and defendants may not be enjoined from saying that in *very* careful fashion.* Should they choose to do this it will undoubtedly require a disclaimer incorporating the conclusion in paragraph 4, below.

4. Whatever efficacy HF has for its intended purpose is not explained by or supported by contemporary, recognized scientific studies or other such evidence.

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*It is hoped that this language won't cause further serious problems. It is obviously meant to preclude overstating the defendants' claims and will be construed to ensure that doesn't happen.

Defendants must be enjoined from making any claims about HF which could be so interpreted.

5. The interests of justice and the public will not be served by any relief other than that expressed above. Specifically, there is no reason for "disgorgement of profits" or anything else along that line. The general public as a whole has not been at all damaged. Individuals who may be perceived to have been damaged have been so in very modest amounts and have had – albeit rarely exercised – a right to recompense. Further, it is not at all clear that defendants have been milking a scam. They had good reason based on their own evidence to resist the relentless governmental pressure to shut their business down, as this memorandum may attest.

Counsel for the parties will meet and confer, at least by telephone conference and electronic mail, with a view to working out definitive findings of fact and conclusions of law and form of judgment. These will be filed and served as early as practicable.

The Court has considerable confidence that very able counsel for both sides will accomodate themselves to this order without much further judicial involvement, at least at the trial level. Uncertainty about the precise form of defendants' future promotional materials, however, does present the possibility (not encouraged) of proceedings addressed to their compliance with the judgment.

/s/ Richard A. Gadbois Jr.
RICHARD A. GADBOIS, JR.
United States District Judge

Dated: 11/30/90

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In the Supreme Court of the United States

OCTOBER TERM, 1994

PANTRON I CORPORATION, ET AL., PETITIONERS

v.

FEDERAL TRADE COMMISSION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

DREW S. DAYS, III
Solicitor General
Department of Justice
Washington, D.C. 20530
(202) 514-2217

JAY C. SHAFFER
Acting General Counsel

ERNEST J. ISENSTADT
Assistant General Counsel

MELVIN H. ORLANS
Attorney
Federal Trade Commission
Washington, D.C. 20580

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QUESTIONS PRESENTED

1. Whether the court of appeals erred in ruling that it is a violation of Sections 5 and 12 of the Federal Trade Commission Act (FTC Act), 15 U.S.C. 45 and 52, to promote the effectiveness of a hair growth product that has no inherent pharmacological efficacy, but works only by means of a placebo effect.

2. Whether the court of appeals erroneously shifted the burden of proof of product efficacy to petitioners.

3. Whether the court of appeals erred in concluding that petitioners' evidence of product effectiveness could not rebut the Federal Trade Commission's evidence of ineffectiveness because petitioners failed to account for the placebo effect.

4. Whether the court of appeals in fact ruled that a district court never has discretion under Section 13(b) of the FTC Act, 15 U.S.C. 53(b), to refuse to award monetary equitable relief.

5. Whether the court of appeals erred in directing an award of monetary equitable relief in this case, even though some consumers may have experienced satisfactory results due solely to a placebo effect.

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BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-42) is reported at 33 F.3d 1088. The district court's judgment, findings of fact and conclusions of law, and memorandum of opinion and intended judgment (Pet. App. 45-67) are not yet reported.

JURISDICTION

The judgment of the court of appeals was entered on August 25, 1994. A petition for rehearing was denied on November 16, 1994. Pet. App. 43. On February 9, 1995, Justice O'Connor entered an order extending the time within which to file a petition for a writ of certiorari to and including March 16, 1995.

The petition for a writ of certiorari was filed on March 1, 1995. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioners are the Pantron I Corporation (Pantron) and Pantron's president and sole owner, Hal Lederman. Petitioners market an anti-baldness nostrum called the "Helsinki Formula." The Helsinki Formula is a non-prescription, topically applied product that typically consists of a conditioner and a shampoo. The allegedly active ingredients in the Helsinki Formula are polysorbate 60 and polysorbate 80, two chemicals found in a wide variety of consumer products, including many foods. Petitioners sell a three-months' supply of the Helsinki Formula for $49.95, plus shipping and handling charges. Pet. App. 3-4, 49-51.

The Helsinki Formula has been heavily promoted through print advertisements and television commercials (including late-night infomercials hosted by the "Man from U.N.C.L.E.," Robert Vaughn). Petitioners' widely disseminated advertising for the Helsinki Formula represents that the product is effective in arresting hair loss and promoting hair regrowth, and also that its effectiveness has been established by reliable and authoritative scientific studies.[1] Pet. App. 4-5, 51. The probative medical and scientific

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[1] For example, the television advertisements referred to "the Helsinki Formula breakthrough, a product that has actually been found to stop hair loss and even rejuvenate hair growth." Pet. C.A. Supp. Exc. R. 13. The advertisements also stated that the Helsinki Formula was "developed by medical doctors, and tested by medical doctors with a very high rate of success." *Id.* at 14.

evidence clearly establishes, however, that any perceived effectiveness of the Helsinki Formula is attributable solely to its "placebo effect."[2] *Id.* at 19-21. In other words, the Helsinki Formula has no inherent, or pharmacological, effect in treating baldness.[3] See *ibid.*

Petitioners were aware that their effectiveness claims for the Helsinki Formula were unsupported by valid scientific evidence. From 1982 through 1989, petitioners were informed by the Food and Drug Administration, the United States Postal Service, the Los Angeles District Attorney, and even the National Advertising Division of the Council of Better Business Bureaus that claims of efficacy and scientific support for the Helsinki Formula were inaccurate and unfounded. Pet. App. 4-5, 36-38. Nonetheless, petitioners persisted in making those false and deceptive claims. See *ibid.*

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[2] The "placebo effect" refers to the positive results that may be obtained from use of an inactive drug due to psychological or other reasons, rather than to any pharmacological effect. Pet. App. 2 n.1. In the case of purported hair growth products like the Helsinki Formula, the placebo effect has both a subjective component (arising from consumers' misperceptions of hair growth) and an objective component (actual, measurable hair growth that is likely caused, not by any pharmacological effect of the drug, but from the scalp stimulation associated with massaging any substance, including plain water, into the scalp on a regular basis). *Id.* at 21.

[3] The Federal Food and Drug Administration (FDA) has issued a regulation prohibiting marketers of all nonprescription products from making any baldness treatment claims on their labels. See 21 C.F.R. 310.527. The FDA regulations govern labeling, not advertising, and thus do not directly proscribe the conduct at issue in this case.

2. On November 14, 1988, the Federal Trade Commission filed a complaint in district court, pursuant to Section 13(b) of the Federal Trade Commission Act (FTC Act or Act), 15 U.S.C. 53(b), alleging that petitioners were engaged in unfair and deceptive marketing practices and in the dissemination of false advertisements, in violation of Sections 5(a) and 12 of the Act, 15 U.S.C. 45(a) and 52. The Commission sought permanent injunctive relief and monetary equitable relief in the form of restitution or disgorgement. Pet. App. 5. On September 24, 1991, the court issued findings of fact and conclusions of law, and on July 22, 1992, rendered its final judgment. In its final decision, the court granted in part and denied in part the Commission's request for permanent injunctive relief, and denied completely the Commission's request for monetary equitable relief. *Id.* at 45-67.

In its decision, the district court agreed with the Commission that petitioners' advertisements in fact made the two challenged representations, namely, that the Helsinki Formula is effective to arrest hair loss and to promote hair regrowth, and that the product's efficacy is demonstrated by recognized scientific studies. The district court concluded, however, that the claims of efficacy were not false or misleading, because it believed that there was "no evidence * * * to support a contention that the Helsinki Formula is wholly ineffective." Pet. App. 51, 61. The court reasoned that the evidence supporting the Helsinki Formula's effectiveness, while "no[t] scientifically valid" (*id.* at 54), was nonetheless sufficient to establish that the product "most probably works some of the time for a lot of people." *Id.* at 53, 61. As for petitioners' claims of scientific

support, the court ruled that the Commission had established, "by a bare preponderance of the evidence," that such claims "are unjustified in light of modern and accepted standards for research/analysis and scientific reporting." *Id.* at 54.

In its final judgment, the court granted the Commission a limited permanent injunction. Although the injunction prohibited misrepresentations of product efficacy, it permitted petitioners to advertise that "the Helsinki Formula is effective to some extent for some people in dealing with male pattern baldness," if that claim was accompanied by disclosures that the product's effectiveness is more likely to involve arrest of hair loss than hair regrowth, and is not explained or supported by scientific studies recognized under current standards in this country. Pet. App. 46. The injunction also prohibited representations of scientific support, but permitted petitioners to state that the Helsinki Formula "was the subject of medical investigative work by responsible European physicians," if petitioners disclosed that the work did not conform to recognized standards in this country. *Ibid.*

The district court refused to award disgorgement of profits or other monetary equitable relief. It reasoned that there was no consumer injury because individuals "who may be perceived to have been damaged have been so in very modest amounts," and because Pantron's customers "had—albeit rarely exercised—a right to recompense" through petitioners' advertised money-back guarantee. Pet. App. 67. The court also ruled that the Commission had not established, for purposes of demonstrating individual liability for monetary relief, that petitioner Leder-

man knew or should have known that Pantron's conduct was dishonest or fraudulent. *Id.* at 59.

3. The Commission appealed the district court's rulings that petitioners' claims of product efficacy were not false or misleading, and that petitioners should not be ordered to pay monetary equitable relief. The court of appeals reversed and directed the district court to modify its injunction to prohibit petitioners from making any representations that the Helsinki Formula is effective in arresting hair loss or promoting hair regrowth. The court of appeals also directed the district court to order petitioners to pay monetary equitable relief. Pet. App. 1-42.

On the issue of liability, the court of appeals held that the district court had committed legal error by requiring the Commission to prove that the Helsinki Formula was "wholly ineffective" to show that petitioners' representations of product efficacy were false advertisements or deceptive practices. The court of appeals concluded that the standard applied by the district court was legally incorrect because it imposed on the Commission the impossible burden of demonstrating that the Helsinki Formula did not have even a placebo effect. The court reasoned that, where the evidence demonstrates that a product's effectiveness arises solely as a result of the placebo phenomenon, a representation that the product is effective is false and deceptive for purposes of the FTC Act. Pet. App. 19, 27.

The court of appeals also concluded that the district court's reasons for denying monetary equitable relief were inadequate as a matter of law, and that application of the correct legal principles to the undisputed facts required monetary relief. Specifically, the court of appeals rejected as legally

insufficient the three grounds given by the district court for denying monetary relief—that economic injury alone was insufficient; that modest individual economic injury was not compensable; and that the existence of a money-back guarantee precluded such relief. Pet. App. 34-35. Because "an application of the proper [legal] principles compels an order of monetary relief," the court of appeals instructed the district court to enter an order requiring the payment of monetary equitable relief, in an amount equal to Pantron's unjust enrichment. *Id.* at 35-36.

Finally, the court of appeals ruled that the district court abused its discretion in refusing to hold petitioner Lederman personally liable for monetary relief. The court held that the evidence before the district court "clearly established that Lederman acted with at least 'reckless indifference to the truth or falsity' of Pantron's representations that scientific support existed for its efficacy claims." Pet. App. 36. The court also concluded that there was "no doubt from the record that Lederman was aware of a high likelihood that the company's claims of scientific support were false." *Id.* at 37.

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or any other court of appeals. Further review therefore is not warranted.

1. Petitioners contend (Pet. 13) that the court of appeals erred in prohibiting them from making efficacy claims for their Helsinki Formula hair growth product because, even if those claims were based solely upon the product's placebo effect, the claims were nonetheless "truthful." It has long been

recognized, however, by the Commission and reviewing courts in cases under the FTC Act, and by the courts in the context of other consumer-protection statutes, that it is unlawful to promote the efficacy of a product that works only by means of a placebo effect. See, *e.g.*, *Bristol-Myers Co.*, 102 F.T.C. 21, 336 (1983), enforced, 738 F.2d 554 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985); *Warner-Lambert Co.*, 86 F.T.C. 1398, 1495-1496 (1975), aff'd as modified, 562 F.2d 749 (D.C. Cir. 1977), cert. denied, 435 U.S. 950 (1978); see also *United States* v. *An Article . . . Acu-Dot*, 483 F. Supp. 1311, 1314-1315 (N.D. Ohio 1980) (misbranding under Food, Drug, and Cosmetic Act); *Original Cosmetics Prods.* v. *Strachan*, 459 F. Supp. 496, 506 (S.D.N.Y. 1978) (use of mails to obtain money through false representations), aff'd mem., 603 F.2d 214 (2d Cir.), cert. denied, 444 U.S. 915 (1979). As the Commission has explained, it "cannot accept as proof of a product's efficacy a psychological reaction stemming from a belief which, to a substantial degree, was caused by [the marketer's] deceptions." *Warner-Lambert Co.*, 86 F.T.C. at 1496. Similarly, under the Federal Food, Drug, and Cosmetic Act, a label is considered "misleading" where "the device is not *inherently* effective, its results being attributable to the psychosomatic effect produced by the advertising and marketing of the device." *Acu-Dot*, 483 F. Supp. at 1315.

Were a placebo effect sufficient to establish efficacy for purposes of the FTC Act, then sugar pills could lawfully be advertised for the relief of pain, since "[p]eople who are given medication for an ailment frequently feel better because they think they should, even though the product has no therapeutic value." *Warner-Lambert Co.* v. *FTC*, 562 F.2d at 754 n.9.

Hence, far from creating a "new category of false advertisement" (Pet. 11), the decision of the court of appeals merely recognizes the well established, common sense principle that a product may not be promoted as effective if the product works no better than a placebo.

Petitioners argue (Pet. 11) that the court of appeals' construction of the FTC Act would prohibit truthful statements in advertising. It has long been clear, however, that the FTC Act proscribes even literally truthful statements when such statements might reasonably be interpreted in a misleading manner.[4] Thus, petitioners' efficacy claims, even if literally true because of the placebo effect, are misleading because the product is not "*inherently* effective."[5] As the court of appeals observed, consumers purchasing a hair growth product such as the Helsinki Formula undoubtedly do so in the belief that the product has some therapeutic, pharmacological, value. Pet. App. 27.

The misleading and deceptive nature of petitioners' advertising claims is not cured by either the existence of some satisfied consumers or the fact that the Helsinki Formula is not unsafe. Evidence of consumer satisfaction is meaningless in a case of this kind; by definition, such evidence will exist whenever

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[4] *Thompson Medical Co.* v. *FTC*, 791 F.2d 189, 197 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987); *Feil* v. *FTC*, 285 F.2d 879, 896 n.27 (9th Cir. 1960); *Koch* v. *FTC*, 206 F.2d 311, 317 (6th Cir. 1953).

[5] *Acu-Dot*, 483 F. Supp. at 1315; see *Original Cosmetics Prods.*, 459 F. Supp. at 506; *Bristol-Myers Co.*, 102 F.T.C. at 336; *Warner-Lambert Co.*, 86 F.T.C. at 1496.

there is a placebo effect.[6] Also meritless is petitioners' suggestion (Pet. 14) that, because the Helsinki Formula poses no risk of physical harm, its promotion as an effective hair growth product should be countenanced based on its placebo effect alone. As the court of appeals noted, "a major purpose of the [FTC] Act is to protect consumers from economic injuries." Pet. App. 34. The FTC Act protects consumers from being misled into paying for products that are worthless, even if those products are not harmful to their health.

2. Petitioners argue (Pet. 15-19) that the court of appeals inappropriately shifted the burden of proof to them to show that their product was effective. That contention is incorrect. The court of appeals ruled that the district court erred in requiring the Commission to carry the insurmountable burden of proving that the Helsinki Formula was "wholly ineffective." Pet. App. 24. The district court erred as a matter of law by accepting a placebo effect as proof of efficacy; as a consequence of that mistake, it erred further by requiring the Commission to negate even the possibility of a placebo effect to prove that petitioners' efficacy claims were misleading and violated the FTC Act. See *id.* at 19, 24, 27. As the court of appeals explained, it is misleading under the

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[6] In addition, consumers have difficulty in evaluating the efficacy of the Helsinki Formula because hair loss proceeds at an irregular rate (Pet. App. 22a; Tr. 88-89; Pons Dep. 88), and because the Helsinki Formula contains ingredients that coat the hair and make it appear thicker (Pons Dep. 86). These factors would all lead consumers incorrectly to attribute perceived improvement to a supposed pharmacological effect. Cf. *American Home Prods. Corp.* v. *FTC*, 695 F.2d 681, 698 (3d Cir. 1982); *Warner-Lambert Co.*, 86 F.T.C. at 1495-1496.

FTC Act to promote as effective a product that works only by means of a placebo effect, even though some consumers may experience positive results. *Id.* at 27. The court of appeals correctly held that, to prevail, the Commission was required only to "demonstrat[e] that the [Helsinki Formula] has no force beyond its placebo effect." *Id.* at 19.

Although the court of appeals corrected the legally erroneous burden of proof imposed by the district court, the burden of persuasion nonetheless remained at all times on the Commission to demonstrate that the Helsinki Formula was no more effective than a placebo.[7] Assessing the totality of the evidence under the correct legal standard, the court of appeals concluded that "[t]he evidence before the district court made clear that there is no reason to believe that the Helsinki Formula is at all effective outside of its placebo effect." Pet. App. 29. In other words, the court of appeals ruled that the Commission had carried the proper burden of proof.

3. Petitioners also argue (Pet. 16-17) that the court of appeals erred in rejecting evidence of scientific support for the pharmacological efficacy of

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[7] As in the typical case, the Commission was required to produce evidence sufficient to establish a *prima facie* case, and the burden of production (but not the burden of persuasion) then shifted to petitioners to rebut the Commission's case by presenting evidence that the Helsinki Formula was effective beyond its placebo effect. See generally *Director, OWCP* v. *Greenwich Collieries*, 114 S. Ct. 2251, 2255-2257 (1994). Petitioners could have carried their burden of production by producing evidence, such as valid and reliable placebo-controlled studies, demonstrating that the Helsinki Formula was more effective than a placebo, but they were unable to do so.

the Helsinki Formula merely because that evidence would not satisfy standards acceptable to the "American medical community." That argument misapprehends why the court of appeals rejected petitioners' purported evidence of scientific support. As the court of appeals recognized, the Commission put forth substantial scientific evidence demonstrating that the Helsinki Formula has no effectiveness beyond its placebo effect—consisting, *inter alia*, of the testimony of three medical experts, the consensus view of the medical/scientific community, and a published, peer-reviewed, double-blinded, placebo-controlled clinical study concluding that one of the supposedly active ingredients of the Helsinki Formula has no effect on hair growth. See Pet. App. 5-9, 19-20. In contrast, petitioners' evidence consisted of studies that did not meet basic scientific norms (including one "uncontrolled, unblinded, unrandomized, un-peer-reviewed study," and other similarly defective studies) and the testimony of two physicians based on those studies. *Id.* at 9-11. None of petitioners' evidence accounted or controlled for the placebo effect, which was acknowledged by petitioners' experts as well as the Commission's, *id.* at 20, 24, and therefore none of it was capable of rebutting the strong evidence that polysorbate-based products such as the Helsinki Formula are no more effective than a placebo. *Id.* at 21-23.[8]

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[8] Petitioners maintain (Pet. 17) that rejection of their evidence of customer satisfaction is tantamount to suggesting that "consumers are *too stupid* to know what is good for them and incapable of determining whether their hair is growing or whether their hair loss is decreasing." But the existence of a substantial placebo effect, in combination with other factors (*e.g.*, the irregular rate of hair loss and the inclusion in the

4. Petitioners argue (Pet. 19-23) that the court of appeals erred in ruling that a district court, acting under Section 13(b) of the FTC Act, may not, in the exercise of discretion, decline to award monetary equitable relief (*i.e.*, restitution or disgorgement). The court of appeals made no such ruling, however; it held only that the district court had denied monetary relief based on the application of erroneous legal principles, and that application of the proper principles to the facts of this particular case compelled an order of monetary relief. See Pet. App. 35. The court of appeals then remanded the case to the district court, with instructions to order petitioners to pay monetary equitable relief, in an amount to be determined by the lower court. *Id.* at 35 & n.34, 36, 38, 42. Cf. *Albemarle Paper Co.* v. *Moody*, 422 U.S. 405, 416 (1975) ("[S]uch discretionary choices are not left to a [district] court's 'inclination, but to its judgment; and its judgment is to be guided by sound legal principles.'") (quoting Marshall, C.J., in *United States* v. *Burr*, 25 F. Cas. 30, 35) (C.C. Va. 1807) (No. 14,692(d)).

In reaching its conclusion that monetary relief was required in this case, the court of appeals correctly rejected, as legally insufficient and even contrary to common sense, the three premises for the district court's refusal to award monetary relief. First, the court of appeals overturned the district court's conclusion that such relief should not be awarded when "consumer injuries have been only economic in

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Helsinki Formula of an ingredient that coats the hair and makes it appear thicker), amply demonstrates that consumers may well be incapable of evaluating whether the Helsinki Formula has any inherent effect. Pet. App. 22.

nature." Pet. App. 34; see *id.* at 57. The district court's error in that respect is self-evident; since a major purpose of the FTC Act is to protect consumers from economic injuries, the remedy of restitution to correct unjust enrichment is "particularly suited" to the FTC Act, and to deny restitutionary relief would "pervert the purposes of * * * the Act." *Id.* at 34. Second, the court of appeals rejected the district court's reliance on the fact that each consumer had suffered only a modest economic injury; as the court noted, "consumer injury is substantial when it is the aggregate of many small individual injuries," and to deny disgorgement on the basis of the size of the injury to each consumer would, in effect, condone unjust enrichment. *Ibid.* Third, the court of appeals correctly rejected the district court's reliance on petitioners' money-back guarantee for dissatisfied customers. If such an offer were dispositive, "the false advertising prohibitions [would be] a nullity," since "[a]nything might then be advertised as long as unsatisfied customers were returned their money." *Id.* at 35. Indeed, many dissatisfied customers will not bother to request a refund, precisely because of the small size of the individual injury, and of course customers deceived by the placebo effect of the product will not request a refund.

Once the court of appeals determined that the district court had committed legal error in denying monetary relief, it was appropriate for the court of appeals to apply the correct legal principles and to order proper redress, rather than merely remanding to the district court without instructions. See 28 U.S.C. 2106 (authorizing courts of appeals to exercise broad discretion on disposition). Since the complete record was before the court of appeals, "there would

be little point in remanding the case merely to allow the [district court] to reconsider its holding under [appropriate legal principles]." *City of Revere* v. *Massachusetts General Hospital*, 463 U.S. 239, 244 n.6 (1983); accord *Quinn* v. *Millsap*, 491 U.S. 95, 106-107 (1989); see, *e.g.*, *FTC* v. *Warner Communications Inc.*, 742 F.2d 1156 (9th Cir. 1984) (court of appeals ordered entry of preliminary injunction after concluding that district court had denied injunction under incorrect legal standards).

5. Finally, petitioners err in contending (Pet. 23) that monetary equitable relief is inappropriate in this case because there are at least some satisfied consumers who presumably believe that the Helsinki Formula is effective. The record demonstrates that any evidence of consumer satisfaction or product effectiveness is attributable solely to a placebo effect. Even satisfied consumers are entitled to monetary relief, for they were deceived into purchasing a product that they were misled to believe had some inherent pharmacological value.

Moreover, it is settled law that the existence of some satisfied consumers does not constitute a defense under the FTC Act. See, *e.g.*, *FTC* v. *Amy Travel Service*, 875 F.2d 564, 572 & n.7 (7th Cir.), cert. denied, 493 U.S. 954 (1989); *Basic Books, Inc.* v. *FTC*, 276 F.2d 718, 721 (7th Cir. 1960); *Independent Directory Corp.* v. *FTC*, 188 F.2d 468, 471 (2d Cir. 1951). The Commission "need not prove that every consumer was injured." *Amy Travel Service*, 875 F.2d at 572. At most, petitioners' argument might warrant the exclusion, on remand, of any demonstrably satisfied consumers (*e.g.*, consumers who repurchased the product or otherwise attested to its

perceived effectiveness) in computing the amount of monetary equitable relief. See *id.* at 572 & n.7.[9]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

DREW S. DAYS, III
Solicitor General

JAY C. SHAFFER
Acting General Counsel

ERNEST J. ISENSTADT
Assistant General Counsel

MELVIN H. ORLANS
Attorney
Federal Trade Commission

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[9] The court of appeals remanded the case to the district court to permit it to "tailo[r] the appropriate monetary relief." Pet. App. 35 n.34.